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(11) EP 1 226 806 A2

(12)

## EUROPEAN PATENT APPLICATION

(43) Date of publication:  
31.07.2002 Bulletin 2002/31

(51) Int Cl.7: A61J 7/00

(21) Application number: 02075754.8

(22) Date of filing: 18.10.1996

(84) Designated Contracting States:  
AT BE CH DE DK FR GB IE IT LI NL SE

(30) Priority: 18.10.1995 US 544623  
03.05.1996 US 642484

(62) Document number(s) of the earlier application(s) in  
accordance with Art. 76 EPC:  
96936716.8 / 0 855 894

(71) Applicant: Telepharmacy Solutions, Inc.  
Billerica, Massachusetts 01862 (US)

(72) Inventors:  
• Liff, Harold J.  
Lexington, MA 02173 (US)  
• Hart, Brian T.  
Bedford, MA 01730 (US)

• Wallace, Robert L.  
Pepperell, MA 01463 (US)  
• Berube, Arthur A.  
Hampstead, NH 03841 (US)  
• Hart, Richard D.  
Irving, TX 75062 (US)

(74) Representative: Greenwood, John David et al  
Graham Watt & Co.  
St. Botolph's House  
7-9 St. Botolph's Road  
Sevenoaks Kent TN13 3AJ (GB)

### Remarks:

This application was filed on 26 - 02 - 2002 as a  
divisional application to the application mentioned  
under INID code 62.

### (54) A method for controlling a drug dispensing system

(57) An automated drug dispensing system includes a cabinet adapted to store a variety of prepackaged pharmaceuticals in a plurality of bins for filling patient prescriptions. Each bin stores a particular variety of packaged multiple-dose pharmaceutical. Each variety of pharmaceutical is associated with a particular code. A controller receives request signals and in response

generates dispense signals. Each bin includes a dispenser coupled to the controller for dispensing the packaged pharmaceuticals therefrom in response to a dispense signal sent from the controller. After a package is dispensed, a code reader determines the code of the dispensed package and verifies whether the code on the dispensed package matches the code of the requested package.

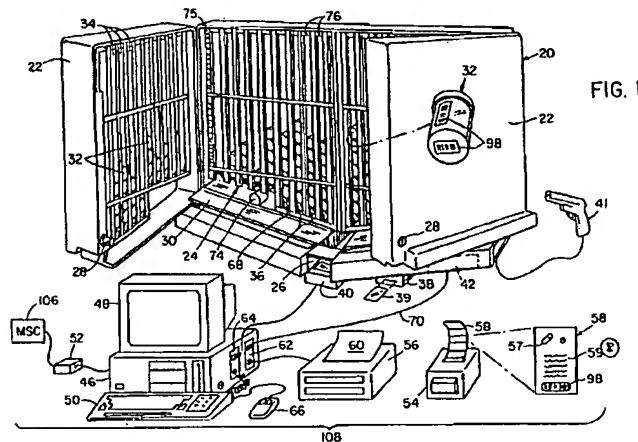


FIG. 1

DescriptionRelated Applications

[0001] This application is a Continuation-in-Part of U.S. Serial No. 08/642,484, filed May 3, 1996, which is a Continuation-in-Part of U.S. Serial No. 08/544,623, filed October 18, 1995. The entire contents of the above applications are incorporated herein by reference.

Background of the Invention

[0002] Automated pharmaceutical delivery systems have been in use for over thirty years. The initial purpose of such systems was to reduce the high rates of medication errors associated with manual distribution. In modern times, automated systems present more sophisticated advantages. These include: further reduction of errors, lower costs associated with pharmaceutical distribution, reduction of personnel, inventory control, substance control, automated documentation, and relieving professional pharmacists of many tasks.

[0003] The current state of the art of automated pharmaceutical delivery systems, otherwise known as medication management devices generally fall under three categories: automated devices in the central pharmacy area; automated devices in the patient care unit; and point-of-care information systems.

[0004] The primary goal of centrally-located devices is to replace or improve the current manual process for filling unit dose carts. These devices offer the advantage of a single, centralized inventory and a lower overall inventory. Disadvantages of such devices include their large size, high cost, and reliance on efficient delivery systems.

[0005] Patient care unit-based devices replace the traditional manual unit dose cart filling and delivery system and provide increased control over floor stock. Advantages of such systems include their smaller size and lower cost relative to centrally-located devices, immediate access to medications, and automated documentation of medication administration. Disadvantages include application to unit dose levels only, increased costs due to the maintenance of multiple inventories in multiple units, additional time required to restock multiple devices, and larger inventory.

[0006] Point-of-care systems are designed to enable immediate exchange of patient data at the bedside. Such systems allow for rapid access to patient information, fast documentation, integration of hospital information systems, and immediate verification of drug administration. Primary disadvantages of point-of-care systems include high cost associated with placing hardware in each room, networking the system, and security issues associated with personal data access.

[0007] The above-described systems offer solutions for medication management in large hospitals where the large expense associated with large centrally-located

pharmacy systems, decentralized patient care units, and point-of-care systems at the bedside are justifiable for unit-dose dispensing and verification. These systems fail to address efficient and economical medication management at medium size facilities, for example health maintenance organizations which cannot justify the expenses associated with the large and costly aforementioned systems. Furthermore, while the above systems provide a solution for unit-dose dispensing for individual patients, they fail to address the issue of filling weekly or monthly prescriptions in a cost-effective manner.

Summary of the Invention

[0008] The present invention combines computer hardware and software, a telecommunications capability, and a medication container dispensing cabinet to form a complete in-office dispensing system. This enables drug prescription dispensing in volume by a physician, pharmacist, or other licensed practitioner directly to the patient at a clinic, group practice, or other location outside a pharmacy or hospital. The system provides a convenient, safe, automated, and low cost drug delivery system for the patient.

[0009] The present invention is directed to an apparatus and method for automated dispensing of packaged pharmaceuticals. The apparatus of the invention includes a cabinet housing for storing a variety of packaged pharmaceuticals in a plurality of bins. Each bin stores a particular variety of packaged pharmaceutical where each package typically contains a plurality of unit doses as normally provided in a pharmacy filled prescription. Each variety of pharmaceutical is associated with a particular code marked on the package. When the packaged items are loaded into the system, the loader scans each bar coded package with a bar code reader so that the data base for the unit properly reflects the packages contained in the unit. For dispensing, a controller receives request signals and in response generates dispense signals. Each bin includes a dispenser coupled to the controller for dispensing a packaged pharmaceutical therefrom in response to a dispense signal sent from the controller. When the package is dispensed, a code reader determines the code of the dispensed package and verifies whether the code of the dispensed package matches the code of the requested package.

[0010] The dispensing process can be initiated by an authorized user at a computer terminal connected to the cabinet controller. Alternatively, a computer can be used to program a card or slip with patient information, with the cabinet being adapted for receiving the card, for automatic dispensing directly to the patient.

[0011] A plurality of the cabinet housings can be installed in a modular or daisy-chained configuration in which a single controller operates a plurality of housings. In a preferred embodiment of the apparatus of the

invention, the bins are in the shape of vertically-disposed columns shaped to store a plurality of bottles stacked vertically. Each bottle is sealed and contains a selected number of doses prior to being dispensed. Pharmaceutical packages are laid on top of each other within each column and are fed by gravity from the top of the column and exit at the bottom of the column on a first-in-first-out basis. Each column includes a replaceable label containing a code which matches the code disposed on the packages placed in that column. Package coding is preferably accomplished by bar code which can include the drug identification number, dosage expiration date and number of tablets. The controller is preferably a computer. In an automated system, sensors mounted in the bins monitor the inventory of the packages in each bin and detect jammed bins.

[0012] The cabinet is preferably mounted on a wall or on a supporting cart as a stand alone unit. A ramp delivers a dispensed pharmaceutical to a drop point. The ramp is preferably sloped so that gravity delivers the dispensed pharmaceutical without the need for other conveying means. A label printer is coupled to the controller for printing a patient specific prescription label for attaching to a dispensed pharmaceutical package. The prescription label can include a printed picture of the pharmaceutical contained in the package. A document printer is likewise coupled thereto for printing instructions specific to the dispensed pharmaceutical for use by the patient or medical practitioner. In a preferred embodiment, the printers are inhibited until the bar-code reader verifies that proper dispensing of the pharmaceutical has occurred.

[0013] A preferred method of using the invention for a clinical trial includes dispensing a pharmaceutical and a placebo in different packages and monitoring use thereof. Clinical trials are commonly used in the evaluation of the safety and effectiveness of drug protocols in the pharmaceutical industry. These trials can typically take the form of distributing the drug being tested and a placebo to a selected patient population and then monitoring the outcome to determine the drug's effectiveness. The dispensing system of the present invention is particularly well suited to aid in the controlled distribution of both the drug (or drugs) under test and the placebo used in these clinical trials. Due to the accurate labelling, record keeping and remote distribution capabilities, and the ability to dedicate specific units to a particular trial the conduct of these trials can be done more safely and accurately.

#### Brief Description of the Drawings

[0014] The foregoing and other objects, features and advantages of the invention will be apparent from the following more particular description of preferred embodiments of the invention, as illustrated in the accompanying drawings in which like reference characters refer to the same parts throughout the different views. The

drawings are not necessarily to scale, emphasis instead being placed upon illustrating the principles of the invention.

5 [0015] FIG. 1 is a diagram of preferred embodiment of an automated drug dispensing system in accordance with the present invention.

[0016] FIG. 2 is a block diagram of an automated system for pharmaceutical distribution and inventory management in accordance with the present invention.

10 [0017] FIG. 3 is a block diagram of a preferred embodiment of a cabinet rack in accordance with the present invention.

[0018] FIG. 4 is a block diagram of an automated drug dispensing system having daisy-chained remote control 15 dispenser cabinets in accordance with the present invention.

[0019] FIG. 5 is a perspective view of a dual-valve dispenser in accordance with the present invention.

20 [0020] FIGS. 6A-6C are sequential illustrations of the operation of the dual-valve dispenser.

[0021] FIG. 7A is a flow diagram of the main menu software.

[0022] FIGS. 7B and 7C are flow diagrams of the prescription menu software.

25 [0023] FIG. 8 is a schematic diagram illustrating the administration of a clinical trial in accordance with the invention.

[0024] FIG. 9 is a schematic diagram of a circuit board using a controller for a drug dispensing system in accordance with the present invention.

30 [0025] FIG. 10 is front view of a dispensing system on a rollable cart in accordance with the invention.

[0026] FIGS. 11A and 11B are block diagrams of system configurations in accordance with the present invention.

35 [0027] FIG. 12 is a flow diagram representing the processes performed by the pharmacy technician at an RCD and a registered pharmacist at an RPH in accordance with the present invention.

40 [0028] FIGS. 13A-13Q are flow diagrams representing the software operating on the remote pharmacist (RRPH) workstations.

[0029] FIGS. 14A-14V are images of the user interface for the RPH workstation software.

45 [0030] FIG. 15 is a printout of a patient monograph to be administered to the patient along with labels for adherence to the dispensed pharmaceutical in accordance with the present invention.

[0031] FIG. 16 is a block diagram representing a variety of remote drug dispensing configurations in accordance with the present invention.

50 [0032] FIG. 17 is a schematic block diagram representing the transfer of data between an RCD host computer and a remote RPH workstation in accordance with the present invention.

55 [0033] FIG. 18 is a schematic block diagram representing connectivity between RCD units at various sites in accordance with the present invention.

[0034] FIG. 19 is a schematic block diagram representing dual modem configuration in accordance with the present invention.

[0035] FIG. 20 is a perspective view of a roller dispenser in accordance with the present invention.

[0036] FIGs. 21A-21C illustrate operation of the roller dispenser during a dispensing sequence.

[0037] FIG. 22 illustrates a direct-drive roller dispenser embodiment in accordance with the present invention.

[0038] FIGs. 23 and 23A illustrate a step column in accordance with the present invention.

[0039] FIG. 24 is a close-up view of an alternative embodiment of a roller dispenser face in accordance with the present invention.

[0040] FIG. 25 is a perspective illustration of a rack of columns in accordance with the present invention.

[0041] FIG. 26 is a perspective illustration of drawers of helix dispensers.

[0042] FIGs. 27 and 28 are close-up views of a dispensing sequence for the embodiment of FIG. 26.

[0043] FIG. 29 is a perspective illustration of a system including helix and column dispensers in accordance with the present invention.

[0044] FIG. 30 is a perspective illustration of a cabinet-style dispensing system in accordance with the present invention.

[0045] FIG. 31 is a perspective illustration of a cabinet used in the system of FIG. 30 in accordance with the present invention.

[0046] FIG. 32 illustrates a dispensing unit having a plurality of workstations in accordance with the present invention.

[0047] FIG. 33 illustrates a kiosk system in accordance with the present invention.

#### Detailed Description of Preferred Embodiments

[0048] The present invention provides safe pharmaceutical prescription dispensing directly by physicians, pharmacists, and other licensed practitioners operating in small to medium size locations in a cost-effective manner. Prepackaged pharmaceuticals are stocked at nearby municipal service centers and distributed to the health care locations as needed. The inventory is continually and automatically monitored by a host computer at the location. Inventory is ordered on a just-in-time basis by the computer. In this manner, prepackaged multiple-dose pharmaceuticals are available to practitioners at the health-care facility for immediate filling of patient prescriptions.

[0049] The present invention offers significant advantages to physician group practices. The system improves customer service and enhances the image of the group practice. Drug theft is prevented by securing the pharmaceuticals in a closed system and inventory is kept low. The system meets state pharmacy, safety, and regulatory compliance laws, whereas many manual dis-

pensing systems do not. A pharmaceutical distributor can handle all inventory planning, financing, maintenance, and ordering with minimal interaction with group practitioners. Disruptive telephone calls to the physician from pharmacists are minimized. Further, physicians can gain immediate access to a patient's pharmacy records currently unavailable to him.

[0050] Managed care providers, for example, Health Maintenance Organizations and Pharmacy Benefits Managers also realize significant advantages from the present invention. The invention increases the likelihood that a patient will receive the required treatment, because the pharmacy is available at the doctor's office. Labor costs for in-house pharmacies are reduced, allowing staff reductions or reassignments. In-house drug dispensing can be extended to physician-staffed satellite clinics and other locations not suitable economically for conventional pharmacies. The system enables automated patient compliance enhancing programs, drug utilization analysis, and the use of other emerging pharmacy management opportunities to reduce costs and improve patient compliance and wellness. Drug costs are reduced by formulary control, thereby encouraging generic substitution of name brand drugs. Inventory is tracked automatically by the drug distributor headquarters, thus preserving professional time for patient care.

[0051] The present invention also offers significant advantages to the patients. Drugs are provided immediately at the physician's office, avoiding an inconvenient trip to a pharmacy. This is particularly important to mobility-impaired patients and eliminates a major source of drug non-compliance. Electronic third-party payor cards can be used for drug purchases at the doctor's office. The patient can obtain prescription drugs at prices competitive with retail discounters. The physicians are able to track prescription compliance which can result in faster recovery.

[0052] The apparatus of a preferred embodiment of the invention will now be described. FIG. 1 is a diagram of an automated drug dispensing system in accordance with the present invention. The primary components of the system include a remote control dispenser (RCD) cabinet 20, a host computer 46, a modem 52, a document printer 56, and a label printer 54. The cabinet 20 includes a rack 24 comprising a plurality of bins, preferably in the shape of columns 34. Packages 32 such as drug bottles, containing pharmaceuticals of various types are distributed among the columns 34, each column 34 containing a separate type of pharmaceutical. Four racks 24 are enclosed in the cabinet 20 chamber, two in the main cabinet 20 and two on the doors 22. The doors are secured by locks 28.

[0053] A licensed user, for example, a doctor, pharmacist, nurse, or other medical practitioner qualified to fill patient prescriptions, operates the system at the host computer 46, using a keyboard 50 and mouse 66 for input and receiving visual feedback at a monitor 48. Using the keyboard 50, a user enters a command to re-

quest dispensing of a particular packaged pharmaceutical variety 32 for a particular patient. The computer 46 transmits the request via an interface 70 to a controller 42 located on the RCD cabinet 20. The controller 42 interprets the command sent from the computer 46 and enables a dispensing actuator 68 in the appropriate column 34. The lowest package 32 in the appropriate column 34 is released from the column 34 and ejected onto a ramp 30. The released package 74 slides down the ramp 30 into an opening 26, where the released package 74 is made available to the dispensing party for transfer to the patient. A bar code reader 40, located near the dispensing opening 26, reads a code 98 on the dispensed package 74 and transmits the bar code information to the computer 46, which informs the user whether the code 98 on the dispensed package 74 matches that which was requested by the user. The bar code 98 can be disposed on the side, top, and/or bottom of the package 32. In an automated embodiment of the system, sensors 36 located on each column 34 monitor the dispensing process and notify the controller 42 of any package jams. The sensors 36 also monitor inventory of the columns 34 and notify the computer 46 through controller 42 that a particular column is empty or near empty.

[0054] Alternatively, the prescription can be dispensed directly to the patient. A card reader 38, mounted directly on or near the cabinet, is adapted to receive a card 39 from a patient. The card is programmed with patient information by a licensed practitioner. The patient inserts the card 39 in the card reader 38 and receives his medication automatically from the cabinet. The medication bottle 32 may be filled with a single dose of medication for a particular patient, or can include weekly or monthly doses. This embodiment is especially useful in large institutions, such as prisons, where many individuals require medication on a regular basis.

[0055] Upon validating the bar-code 98 of the dispensed package 74, the computer generates a label 58 containing prescription information at a label printer 54 to be placed on the package, and generates a document 60 at a document printer 56 containing additional instructions for the patient or practitioner. A modem 52 enables periodic or continuous communication between the host computer 46 and other computers in the network so that a complete inventory and status of each remote control dispenser cabinet is available at all times. Several remote control dispenser cabinets 20 can be integrated into a single installation operated by a single computer 46. The cabinets 20 can each be individually connected to the host computer 46, or may be daisy-chained, with only one cabinet 20 in the chain connected to the host 46.

[0056] A typical remote control dispenser cabinet 20 contains forty columns 34 for holding and dispensing the prepackaged pharmaceuticals. Each rack 24 includes ten columns 34, as shown in FIG. 3. Two racks are disposed on each side of the cabinet, one in the main cab-

inet area 20, and one on the door 22, such that when the door 22 is closed, the racks 24 face each other. A typical column will hold up to 13 packages of a given pharmaceutical. The columns at the ends of the cabinet

5 34A are shorter than the columns nearest the center of the cabinet 34B to accommodate the sloped ramp 30. The ramp 30 receives a dispensed pharmaceutical package, and directs it toward the dispensing area 26 in the center of the cabinet 20. A raised ramp divider 31 10 divides the ramp 30 into two sections 30A, 30B, each section for dispensing pharmaceutical packages from each rack.

[0057] At the top of each column 34 is a replaceable bar code label 76 which identifies the pharmaceutical 15 contained in that column and the appropriate column number. At the time of loading the cabinet, the column bar code label 76 is matched against the package label 98 to be loaded to verify that the correct pharmaceutical package 32 is placed in each column. Referring back to

20 FIG. 1, the RCD controller 42 receives commands from and transmits status information to the host computer 46 via the controller interface 70. A request command sent from the host computer 46 identifies the pharmaceutical package 32 to be dispensed. In response, the

25 RCD controller 42 activates the appropriate dispenser 68, thereby releasing a single package of the variety requested. A parallel or serial I/O interface 62 at the host computer 46 provides a sufficient communication channel

30 from the host computer 46 to the controller 42. A full duplex implementation allows the controller 42 to transfer status information back to the host 46. Status information may include errors such as package jams, empty columns, or other cabinet status. Availability of such information prevents inconsistencies in the database and provides the operator with recovery procedures. This 35 would require adequate sensors 36 to be mounted in appropriate positions on the RCD cabinet 20.

[0058] The bar-code reader 40 can be mounted directly on the unit or can comprise a hand-held unit 41. It verifies proper loading of the RCD cabinet 20 and proper dispensing of each pharmaceutical package 32. Before a column 34 is loaded with packages 32, the column bar code label 76 is compared with the bar code

45 label 98 of each package 32 inserted into the column 34. Each time a package 74 is dispensed from the cabinet 20, the package bar code label 98 is scanned by the bar code reader 40 to verify that the correct pharmaceutical has been dispensed. The bar code reader

50 40 is interfaced to the host computer 46 through a standard keyboard wedge 64. The wedge 64 makes the bar code reader 40 input via the bar code interface 72 appear to be coming from the keyboard 50. Such an interface is a simple and reliable interface to the pharmacy

55 software operating on the computer 46. The bar code reader 40 must be highly reliable and provide a high first read rate. Label printing on the pharmaceutical packages 32 must be of high quality to accommodate this. Dur-

ing loading, the bottles are loaded into each column up to a certain height. the highest bottle in the column is positioned adjacent a bar coded column label 75 running along each column. Thus, the number of bottles in each column can be recorded at loading and tracked during use.

[0059] The host computer 46 runs the pharmacy software, provides a user interface, and supports the RCD controller 42, bar code reader 40, and modem 52. A standard off-the-shelf personal computer and operating system are sufficient to meet these requirements. As described above, the keyboard 50 and mouse 66 receive input from the user and the monitor 48 provides visual feedback. The document printer 56 prints documentation 60 such as detailed instructions and a label printer 54 prints package labels 58, for example, prescription information 59 for adherence to the dispensed package 74. The prescription label 58 may also include a printed picture of the pharmaceutical 57 contained on the bottle to provide additional security.

[0060] The modem 52 provides a communication link between the municipal service center (MSC) 106 and the remote control dispenser 108. Through this link, inventory of each RCD cabinet 20 is automatically monitored and updated in the MSC 106 computer. The modem link also serves as a medium to issue restock orders, update pharmacy software running on the host computer 46, and provide remote diagnostics. The modem can be compatible with standard telephone lines and can be capable of transferring data at sufficient rates.

[0061] The pharmacy software operating on the host computer 46 is a standard commercial software package which provides standard administrative and accounting capabilities. The pharmacy software also supports the unique features of the remote control dispenser system. These include: data communication with the RCD controller 42 via parallel or serial I/O interface 62; data communication with the bar code reader 40 via keyboard wedge 64; data communication with the municipal service center via modem 52; printing of labels 58 with the label printer 54 and printing of documentation 60 with the document printer 56. The software is described in further detail below in conjunction with FIGs. 7A, 7B, and 7C.

[0062] The cabinet 20 and rack 24 are preferably fabricated from aluminum, stainless steel, or plastic to be fully compatible with a clinical setting. The rack 34 can be modified to provide for a diversity of packages including various box and bottle sizes, unit-of-use packaging, liquids, syringes, and various non-prescription products, for example, medical supplies.

[0063] The computer 46 can comprise a portable terminal, a notebook computer, or a hand-held personal digital assistant. Voice recognition or voice prompted software can be employed using a telephone or wireless local area network. Voice recognition systems can use a generic or a user-customized system and can include

voice signatures. The objective is to maximize system flexibility and ease of use for the doctor and staff without compromising safety. The remote control dispenser system can be utilized as a free-standing system, as a local network integrated with physician office computers, or as a centralized network in conjunction with product release at a remote location.

[0064] FIG. 4 is a block diagram of a remote control dispensing configuration having daisy-chained remote drug dispensing units 20. A computer 100 at distribution headquarters is connected through a modem 52 to a bi-directional communication link 118. A computer 106, including disk storage 107 and a printer 56, at the municipal service center 106 communicates with headquarters 100 and with a plurality of remote control dispenser workstations 46 via modems 52. The RCD workstations 46 include a printer 56 and may include personal data assistants 122. The workstation 46 is connected via a controller interface 70 to remote control dispenser cabinets 20. The cabinets 20 can be daisy-chained as shown or may each be individually connected to the workstation 46. The computer 100 can also be linked by modem to all or selected remote dispensers so that each dispenser can be remotely controlled.

[0065] FIG. 5 is a perspective view of a dual-valve dispenser 68. As shown in FIGs. 1 and 3, each column 34 includes a dispenser unit 68. The dispenser unit 68 is located at the bottom of each column for dispensing a single bottle 32 when commanded by the user. A preferred dispenser 68 includes an upper solenoid 80A and a lower solenoid 80B. Each solenoid 80A, 80B engages a corresponding dispenser valve 84A, 84B. The dispenser valves 84A, 84B are biased in a closed position by return springs 82A, 82B. All dispenser components 35 are mounted to a housing 86.

[0066] FIGs. 6A-6C illustrate operation of the dispenser valve during a dispensing sequence. In FIG. 6A, a gravity-fed column of bottles 32 is held in place by a bottle rack 24. A lower bottle 32B is retained by lower solenoid 80B and lower valve 84B and held in place between the valve 84B and the wall of the rack 24. The remaining bottles in the column 32A are retained by the upper solenoid 80A and upper valve 84A.

[0067] In FIG. 6B, the lower solenoid 80B retracts, preventing the lower valve 84B from interfering with the lower bottle 32B. This allows the lower bottle 32B to be released and dispensed. The upper bottles 32A continue to be held in position by upper valve 84A.

[0068] In FIG. 6C, the lower solenoid 80B is reactivated and lower valve 84B again interferes with the rack 24. The upper solenoid 80A is then retracted, disengaging the valve 84A from the upper bottles 32A. This allows the column 32A to fall and the lowest bottle engages the lower valve 84B. The upper solenoid 80A next closes the upper valve 84A, causing it to engage the next bottle 32A in the column. In this manner, a single bottle 32B is dispensed, the remaining bottles 32A all descend one position, and the dispenser 68 is again ready to dis-

pense as shown in FIG. 6A.

[0069] An alternative dispenser, referred to herein as a "roller" dispenser, is illustrated in the perspective view of FIG. 20. Each column 606 includes a roller dispenser unit 622. Each roller has end faces 618, 626, and a side wall 620 in the shape of a sectioned canister. The roller is adapted to rotate about bushings 619. A motor assembly 608 at the top of each column 606 drives a cam 610. A drive cable 612 is coupled to the cam 610 at a proximal end, and a pin 614 on the side wall 620 of the roller 622 at a distal end. As the roller dispenser unit is activated, the motor 608 causes the cam 610 to rotate, which in turn tensions the drive cable 612. This causes the roller 622 to rotate in the direction shown by arrow 623. The roller rotates nearly a half turn and causing a bottle cradled in the hollow portion 624 of the roller to be dispensed. After tension is removed from the drive cable 612, the return spring 616 returns the roller 622 to its original position.

[0070] FIGs. 21A-21C illustrate operation of the roller dispenser 622 during a dispensing sequence. In FIGs. 21A, a gravity fed column of bottles 604A-D is held in place by a bottle rack 606. The lowest bottle 604A in the stack is located in the opening 624 of the roller assembly 622. The remaining bottles 604B-D rest above bottle 604A.

[0071] In FIG. 21B, the motor (not shown) has tensioned the drive cable 612 and tugs on the cable 612 connected to pin 614 on the roller 622. This causes the roller 622 to rotate in the direction shown by arrow 625, thereby dispensing bottle 604A. As the roller rotates, the leading edge 623 comes in contact or "slices" the lower edge of bottle 604B, causing the column of bottles above bottle 604A to raise slightly. The circumferential length of the roller side wall 620 (see FIG. 20) determines when the bottle is released during rotation of the roller. If the length is too long, the bottle will not release from the roller, and if too short, multiple bottle drops may result. A preferred circumferential length will cause the leading edge of the roller side wall 620 to slice the next bottle 604B in the stack enough to lift the stack of bottles a height approximately equal to the material thickness of the roller side wall.

[0072] In FIG. 21C, bottle 604A has been dispensed and the motor releases the tension in the cable 612. The return spring 616 causes the roller to rotate in the direction shown by arrow 623 and return to its original position. At or near its original position, bottle 604B settles into the opening 624 and is ready for dispensing. The remaining bottles 604C,D lower into position above bottle 604B. Various roller dispenser configurations can be realized. For example, the standard spring 616 illustrated in FIG. 20 can be replaced by a coil spring, allowing for a lower profile, and therefore, denser packing of columns. The spring 616 can be replaced by a dual drive cable 612 design, a first cable to rotate the roller clockwise, and a second cable to rotate the roller counter-clockwise.

[0073] In a cable-less design as shown in FIG. 22, the motor 608 is attached directly to the hub 628 of roller 622. The motor causes the roller 622 to rotate and dispense in a 360 degree motion and to be in position for reload. For purposes of the present invention, this configuration will be known as a direct-drive system. In this system, the motor may comprise a step motor preferably geared to match the weight and load of the column of bottles above the roller. Alternatively, a more powerful

5 motor may be used to handle the highest conceivable bottle column weight.

[0074] FIG. 23 is a perspective view of a step column, which allows for columns of larger height. An entirely vertical column is limited by the construction of the bottle 10 as the bottle positioned at the bottom of the column must bear the weight of all bottles above it. For example, a typical pharmaceutical bottle will begin to deform under the weight of 25 bottles. By introducing a step 630 in the 15 column as shown in FIG. 23, the vertical load 633A of the bottles above the step 631 is redirected 633B into the side wall of the column as shown in Inset FIG. 23A. Alternatively, a door 632 may be implemented in the column as shown in FIG. 23 for supporting the weight of the bottles above the door 632. In this configuration, the 20 door may open and close each time a bottle is dispensed.

[0075] FIG. 24 is a closeup view of the interface between the drive cable 612 and an alternative embodiment of the face of the roller 626. In this embodiment, a 25 fitting 640 on the end of the cable 612 interfaces with a mating hole 641 on the roller face 626. A cable housing 613 protects the cable from interference along the length of the column. The cable housing 613 is fixed in place by a cable housing mount 634 mounted against the side wall of the column. The return spring 616 attaches to the roller face 626 at a pin stud 638. The opposite end of the spring is attached to the side wall of the column (not shown). Note that in this embodiment, the cable 612 and the spring 616 interface with the face 30 of the roller 626 rather than the side of the roller 618 as shown in previous embodiments. Many embodiments are conceivable along these lines.

[0076] FIG. 25 is a perspective illustration of a rack 35 642 of columns 603. Each column 603 includes a corresponding roller assembly 622, which is individually addressable by the controller to dispense a bottle 604A as shown. After dispensing, a pusher 644 pushes the dispensed bottle forward into an off-center tilt tray 646 and returns to its original position. The tilt tray 646 rotates in the direction shown by arrow 648 for removal of the dispensed bottle by the operator. Either a return spring or gravity returns the tilt tray 646 to its closed position. Note that the tilt tray 646 when opened by the operator prevents entry of the operator's hand or other objects into the rack area 642 to avoid pilferage.

[0077] To load the columns 603, each rack 642 of columns slides out in the direction shown by arrow 650. Each rack preferably includes a key lock at the top with 40 45 50 55

a keying mechanism which retains the key until the rack is returned to its position, preventing loss of the key. After the columns are filled, the rack is returned to its normal position and the key is removed.

[0078] FIGs. 26 is a perspective illustration of an alternative embodiment of the present invention. In this embodiment, drawers 646 of helix dispensers 648 are contained in a cabinet 650. The helix dispensers 648, when activated, rotate in a single direction 652 as shown in FIG. 27. As the helix 648 rotates, any pharmaceutical packages disposed on the helix are pushed forward toward the front of the cabinet 650. One full rotation of the helix 648 will cause the outermost package 654 to be released as shown in FIG. 28, causing the package 654 to fall into the bin 656. After the package 654 drops into the bin 656, an operator slides open the bin 656 and removes the package. While the bin is open, a door (not shown) blocks the opening between the bin 656 and the dispensing area to prevent pilferage. The helix-dispensing unit described above is particularly suitable for packages of various non-standard sizes, for example boxes, bags, and kits. Larger-sized helixes 648 may be used for larger packages and smaller helixes may be used for smaller packages. The helixes 648 are each individually driven by a stepper motor located in the rear of each tray.

[0079] FIG. 29 is a remote control dispenser embodiment well-suited for use in a doctor's office or in a small clinic. The top unit 660 includes a column dispenser as shown in FIG. 25. The bottom unit 662 includes a helix dispenser as shown in FIGs. 26-28. This combination of dispensers covers a range of package styles for controlled substances, tool kits, and bandages for a typical clinic.

[0080] FIG. 30 is a perspective illustration of a cabinet-style dispensing system. A closet 664 encloses a plurality of cabinets 668. Each cabinet contains several racks 670, having a plurality of columns 672 (See FIG. 31). The racks may be positioned in the top 670A or bottom 670B of the cabinet 668. The top 670A and bottom 670B racks may feed into a single door as shown or multiple doors. This embodiment is particularly well suited for pharmaceutical warehousing or for operation in the pharmacy of a large hospital. Such a system is capable of storing and organizing thousands of different pharmaceuticals, each pharmaceutical being automatically trackable by the software described herein.

[0081] FIG. 31 is a perspective illustration of a typical cabinet 668 used in the system of FIG. 30. Each cabinet 668 includes a plurality of racks 670 (one rack is shown), each rack having a plurality of columns 672. Each column includes a dispensing unit, for example, a roller 622 which is individually addressable. The bottles are dispensed onto a gravity-fed track 674 or onto a conveyor belt which conveys the dispensed bottle to an opening 676 for handling by the operator.

[0082] FIG. 32 is an illustration of an alternative dispensing unit. The unit includes a plurality of workstations

678, each workstation having a corresponding dispensing port 680. The unit further includes a cabinet 682 for storing a variety of pharmaceuticals and a conveyer means 684 for conveying a dispensed pharmaceutical

5 from the cabinet area 682 and for distributing it to the appropriate dispensing port 680. Each workstation 678 also includes a printer for printing labels and instructions as described herein and a bar code reader for verifying that proper dispensing has occurred.

[0083] 10 The workstation can alternatively be configured with integrated voice response software and hardware to permit external initiation of a refill order. In such a configuration, a patient telephones the workstation, enters a secret code and initiates refill dispensing. After dispensing as occurred, the workstation verifies such to the patient indicates a time for pick up. At the next opportunity, the operator of the workstation prepares the bottle label and instructions, and verifies that proper dispensing has occurred.

[0084] 15 In a kiosk configuration as shown in FIGs. 33, a cabinet 686 encloses a carousel-type rotatable cabinet 688 containing a plurality of individually addressable locations 690. Upon receiving a dispensing signal, the carousel 688 rotates to align the correct column 690 with

20 the dispenser 692. The dispenser 692 includes a grabber 694 which removes the bottle from its storage location 696. The grabber 694 conveys the pharmaceutical downward to dispensing drawer 698 and rotates to place the pharmaceutical in the drawer 698. The operator removes the pharmaceutical from the drawer and completes the dispensing process.

[0085] 25 FIGs. 7A-7C are flow diagrams of the computer 46 software. The software is preferably in a user-friendly windows format. In a standard format, the software is accessed on the host computer. Alternatively, the software is accessible by a remote terminal 151 or a pen-based personal data assistant 152 through a remote access gate 153. A splash screen 154 containing the company name, for example is output on the screen and the user is queued for a password 155. If the password is entered correctly, a main menu 156 is generated

30 requesting the user to: access a prescription 156A; print a report or label 156B; investigate the database 156C; communicate with a remote location 156D; service the database 156E; maintain the cabinet 156F; load additional software 156G; and exit 156H. If exit 156H is selected, the program ends 157.

[0086] 35 FIG. 7B and 7C are flow diagrams of the prescription submenu 160. The computer queues the user as to whether he would like to enter a new prescription 161, refill an existing prescription 162, or return to the main menu 163. If the user selects the new prescription 161 option, he is queued for a password 164. The user is next asked to enter the patient name 165. If the name is not known, then a search program 166 can search for the patient name or download the patient name from a mainframe 167. When the patient name is known, the user enters various prescription information and con-

firms that the data entered is correct 169. Next, the software runs a clinical review 170 and determines whether the prescription is proper 171.

[0087] If the prescription is proper, a bottle is dispensed 172 and the bar code of the dispensed bottle is scanned 173. If the bar code does not match that which was expected 174, then a warning is displayed 175, a communication link is set up with headquarters 176 and headquarters is warned 177 of the incorrect dispensing. If the proper medication was dispensed 174, then the computer prints a bottle label 178, generates a clinical review report 179 and conducts OBRA patient education monographs 180. The bottle is then administered to the patient 181 and the computer checks inventory 182 and if inventory is low, the computer communicates with headquarters 183 and orders new inventory 184. The computer then returns to the main menu 156.

[0088] If the user selected the "refill prescription" option 162 at the prescription submenu 160, then the password is checked 185 and the current patient record is displayed 186. The practitioner confirms the data 169 and dispensing takes place in the manner described above.

[0089] FIG. 2 is a block diagram of an automated drug distribution system for maintaining the inventory of the RCD sites 108 in accordance with the present invention. The various RCD sites 108 are stocked with prepackaged pharmaceuticals obtained on a just-in-time (JIT) inventory basis from an FDA-approved drug repackager 102. The repackager 102 obtains unit-dose pharmaceuticals from various manufacturers 104, and repackages the unit-doses into a package containing multiple, prescription-sized doses. The packages must be suitable for use in the remote control dispenser units 108. The drugs are then distributed 112 to municipal service centers 106 which operate as regional distribution facilities in major urban areas. In turn, each municipal service center 106 redistributes 114 the packaged pharmaceuticals to each remote control dispenser 108 in its region.

[0090] The entire system is linked by a communication network 116, 118, 120. The inventory status of each remote control dispenser 120 is communicated to the corresponding municipal service center through a standard telephone link 120. Restocking requests and other inventory information are communicated 118 from the municipal service center 106 to headquarters 100 or any desired combination thereof. Headquarters 100 communicates 116 inventory requirements to the repackager 102. In response, the repackager 102 fills the order and ships the stock to the appropriate municipal service center 106. In this manner, headquarters 100 maintains an automated and continually-updated inventory of all remote control dispensers 108 on a JIT basis.

[0091] The system is further capable of monitoring patient records and billings and can format electronic third party billings for processing by the health care provider. With expanded software, patient records can be ac-

cessed on an integrated basis allowing for monitoring of drug side-effects and compliance.

[0092] In a preferred distribution system, a computer at the distributor headquarters 100 sends a restocking request via communication link 116 to the FDA-approved repackager 102. The repackager 102 fills the order and sends it by overnight air courier to the designated municipal service center 106. At the municipal service center, the drugs are distributed to drivers for specific remote control dispensers 108 in the local community. A driver delivers the drugs and restocks the remote control dispenser 108. As drugs are dispensed from the remote control dispenser 108, the inventory, sales, and restocking requirements are updated and transmitted via telephone link 120 to the computer at the municipal service center 106. The municipal service center computer is linked 118 to a similar computer at the distributor headquarters 100, completing the communication loop.

[0093] Pharmaceuticals are preferably bar-coded at the repackager 102. The pharmaceuticals are tracked using bar code information through each step of the process to the point of sale at the customer. In this way, all transactions are recorded and communicated in real-time to headquarters 100. This integrates accounting, accounts receivable, and inventory management systems, which allows the distributor headquarters to operate with minimal staffing. Each step of the process is self-contained and modular allowing rapid and flexible geographic expansion.

[0094] Each remote control dispenser is preferably placed on an inventory replenishment schedule. The number of weekly supply visits is a function of the rate of inventory usage. A computer record is maintained of prescriptions dispensed and product remaining. If there is a sudden increase in inventory activity, for example if a particular variety of medication is running low, an emergency call is initiated by the remote control dispenser 108 to the municipal service center 106 indicating the need for rapid inventory replenishment. The inventory preferably consists of the most frequently prescribed products used by physicians utilizing the unit. The variety can be adjusted at any time and will vary from location to location.

[0095] A software module can be added to optimize use of the drug dispensing system for the administration of a clinical trial. As shown schematically in Fig. 8, clinical trials under current FDA regulations can be conducted in three phases; Phase I at 194 is to access toxicity; Phase II at 196 is to assess safety; Phase III at 197 is to assess efficacy, and possible Phase IV studies 198 for limited distribution. It is highly desirable to automate these procedures as the prompt and accurate evaluation of new treatments for safety and efficacy can lead to expedited regulatory review and approval.

[0096] The software is formatted to provide for administration of these three phases including the administration of the drug and a placebo in a so-called "double blind" procedure and to print out reports suitable for sub-

mission to the regulatory authority which include detailed data on distribution and dose. The computer records which packages contain placebos and which patients receive them. The computer 100 can record and execute various functions 195 in connection with these studies including printing of reports at printer 56, or communications along telephone line 192 for void activated or voice prompted follow up with the patient 190. These can include contacting the physician to report side effects or other information. A monogram on drug compliance is provided to each patient including drug interaction, side effects or dietary instructions.

[0097] FIG. 9 is a schematic block diagram of an RCD controller in accordance with the present invention. The host computer 46 is coupled to the RCD controller 42 via a standard serial interface, for example, an RS-232 interface. A port P1 receives the serial signal 214 and distributes it to a bidirectional tristate buffer 200. The buffered signal 216 enters a microprocessor 204 where it is decoded.

[0098] The microprocessor 240 decodes the serial signal 216 and activates an individual power blank line 218 and an individual solenoid line 222. The solenoids 212 are partitioned into n power banks 208, one power bank for each rack 24 in the cabinet. Each power bank 208 is activated by a data bus 218 output from the microprocessor 204. The power bank lines 220 are distributed to an array of solenoid selectors 210. The solenoid selectors combine the power bank signals 220 and solenoid signals 222 into an addressable array. If a power bank signal 220 is enabled, then power to the corresponding rack is activated. The solenoid signal 222 enables a particular solenoid 212 in the activated rack for dispensing. The solenoid signal bus 222 is m bits wide for selecting one of the m solenoids in the rack 24.

[0099] As stated above, the RCD cabinets can be daisy-chained so that a plurality of cabinets 20 are controlled by the same host computer 46. A second port P2 on the controller board 42 passes the serial signal 214 to the next board in the chain 224. A station-select switch 202 provides additional decoding so the controller 42 has knowledge of its address in the chain.

[0100] Another preferred embodiment of the invention is illustrated in connection with Fig. 10 where a dispensing cabinet 20 is positioned on a cart 248 having wheels and operable as a stand alone unit. The cart 248 can be used to support the unit relative to a wall surface in conjunction with bolts 250 or other suitable housing support mechanism. The housing support elements 250 can be used to support the cabinets 20 relative to the supporting surface without any other means for support.

[0101] Each cabinet 20 can also be insulated and provided with a cooling system 244 and/or a heating system 246. As illustrated, the cooling system 244 can be contained within the housing 20 on the frame of door panel 240. The heating systems can be used in the same panel 240 or in the adjoining panel 242. This system provides for the heating and/or cooling of selected drugs

that require temperature regulation for storage. Many antibiotics, for example, must be maintained at a temperature of between 40°-50° F to remain viable. One or more temperature sensors 252 can be positioned in the housing to monitor temperatures which can be regulated by controller and be recorded in computer 100 memory.

[0102] The remote pharmacist concept is an extension of the remote control dispensing capabilities of the present invention. A computer workstation is provided to assist a technician or other registered pharmacist in the filling of prescriptions. In general, this comprises several steps which are listed below:

- 15 1) retrieve the patient inquiry data - this defines the patient for whom the prescription is intended; the allergy, drug, and disease states of the patient; and the insurance payor(s) of the patient;
- 20 2) select the drug, signa, and other prescription-related parameters such as "refills authorized", "dispense as written", "compound code", etc.;
- 25 3) select the prescriber identification number;
- 30 4) verify information in steps 1, 2, and 3 against the prescription;
- 35 5) perform drug utilization review (DUR);
- 40 6) submit claim to payor;
- 45 7) dispense and verify drug package;
- 50 8) print and attach patient label to drug package;
- 55 9) verify correct label attached to drug package;
- 60 10) provide patient with label drug package and associated documentation such as receipt, patient counseling text, refill instructions, etc.;
- 65 11) provide patient with oral counseling when required or appropriate.

[0103] In traditional practice, a registered pharmacist physically located at the dispensing site performs all of the above steps. In some contemporary situations, a pharmacy technician may perform steps 1, 2, 3, 6, and 7, and the registered pharmacist will perform steps 4, 5, 8, 9, 10, and 11. In this situation, both the pharmacy technician and the registered pharmacist are located at the dispensing site, where one registered pharmacist may serve several pharmacy technicians.

[0104] In some states it is required by law that a registered pharmacist performs steps 4, 5, 9, and 11. In these states, the registered pharmacist provides cognitive or consultative service and leaves the mechanical tasks associated with filling and dispensing the drug to the pharmacy technician. This allows the registered pharmacist to enhance his contribution to the medical care process by affording the pharmacist with more time to focus on those steps which best utilize the pharmacists training and expertise. The remote pharmacist (RRPH) concept of the present invention enables a registered pharmacist to provide the above-cognitive/consultative services without being physically located at the dispensing site. This is accomplished through use of

modern telecommunications technology in conjunction with a computer-based pharmacy workstation. In this manner, the expertise of a registered pharmacist operating an RPH can be shared among a large number of pharmacy technicians, increasing the level of medical care provided in a cost-effective manner.

[0105] The RPH apparatus and method of the present invention is effective in several configurations. A first configuration is shown in the block diagram of Fig. 11A wherein an RPH 260 services several distinct RCD locations 262A-D. Each RCD 262A-D is at a distinct physical location and is connected to an RPH workstation 260 via a telecommunications link 261A-D, for example, a computer modem. This configuration is appropriate, for example, for servicing several low-volume clinics or emergency rooms where it is not economical to place a pharmacist. The mechanical tasks associated with dispensing the drug can be handled by an RCD pharmacy technician or by a qualified member of the medical or administrative staff. A pharmacist based at the RPH provides the pharmacy expertise needed for an effective dispensing process.

[0106] The configuration of FIG. 11B is applicable in a large volume clinic where several pharmacy technicians operating several remote control dispensers (RCD) units 265A-265D perform the mechanical tasks of steps 1-3 and 7-10 outlined above and a pharmacist operating an RPH workstation 264 performs the cognitive or consultative steps 4-6. In this configuration, the RPH workstation 264 can be, but need not be, located in the same facility as the RCD units 265A-265D. If they are in the same facility, the RPH workstation 264 can be linked to the RCD units 265A-D and an RCD cabinet 266 via a local area network (LAN) 268. In this configuration, a patient presents a prescription to a technician at one of the available RCD terminals 265A-265D. At this terminal, a pharmacy technician performs steps 1-3. The results are transmitted over the network to the RPH workstation, and the pharmacist at the RPH performs steps 4-6. After the pharmacist approves the transaction, the technician at the RCD unit performs steps 7-10. In high-volume situations, dispensing is performed at separate RCD cabinets 266 adapted for dispensing large quantities of pharmaceuticals. A label is printed at a printer 267 and attached to a pharmaceutical package, for example, a bottle. The bar code reader compares the bar codes of the bottle and label to ensure that the proper prescription has been dispensed. If so, the patient is presented the bottle and corresponding documentation.

[0107] FIG. 12 is a flow diagram representing the processes performed by the pharmacy technician at an RCD and a registered pharmacist at the RPH in accordance with the present invention. Initially, a patient presents a prescription to a technician at an RCD unit 270. The technician determines whether the drug is stocked in the RCD unit 271. If the pharmaceutical is not stocked, then the technician decides whether to elec-

tronically transfer via facsimile, email, or otherwise, the prescription to an affiliate 272. If the prescription is transferred to the affiliated pharmacy, 273, the patient may travel to that pharmacy to receive the pharmaceutical. Otherwise, the prescription is returned to the patient 274 to be filled at another RCD unit or by another pharmacist of the patient's choosing.

[0108] If the drug is stocked at the RCD unit, then patient data is retrieved 275, the drug is selected 276, the prescription signa is selected 277 and additional scripts may be entered 278. Following this, the identification number of the prescriber is entered 279 and all data is transmitted to the RPH workstation 280. At the RPH workstation, the pharmacist verifies the prescription 281 and performs a drug utilization review 282. If issues arise during the review, the pharmacist is immediately made aware of the conflict and given an opportunity to review and, if appropriate, override 283 the interventions 284. If the pharmacist decides at this point to discontinue the dispensing 285, the process is aborted 294. If the pharmacist decides to continue the dispensing anyway 284 or there were no interventions 283 in the first place, then claim adjudication is performed 286. During adjudication 286, a patient's insurance information is automatically verified to determine whether the insurer will pay for the prescription, and if so, if any copayment is required from the patient. If a negative response is received 287, drug dispensing is aborted 291. Otherwise, the drug is dispensed and verified with a bar code reader 288. If an improper drug was dispensed, the technician is notified to abort the process as a system failure has occurred 292. Upon system failure electronic notification is performed. Distribution headquarters or a regional dispensing location or agent can be notified by the RCD system of an incorrect dispense is shown. Electronic notification can take the form of a fax, email, file transfer, pager notification, or any other electronic transfer protocol. If verification is positive, a label is printed and affixed to the bottle 290, and the prescription is dispensed to the patient by the technician 293.

[0109] FIGs. 13A-13Q are flow diagrams representing the software operating on the remote pharmacist (RRPH) workstation 314. The system is accessible in a variety of configurations and on a variety of platforms including a pen computer 301, a laptop computer 302, and a workstation 314 accessing the system either at an on-site location or through a telephone network 305. The pharmacist can also access the system via telephone modem 305 from a remote location 304 anywhere in the world. The operating system is preferably a windows-based system, for example, OS/2™, Windows 95™, or Windows NT™. A programming language, for example, OS Visual Basic™, Borland Delphi™ and various tool kits such as OCX-VBX Library Kits and ButtonMaker™ by FarPoint Technologies™ provide the framework for supporting the Windows environment. The windows environment is preferably mouse-driven and may optionally employ voice-activat-

ed technology touch screen, or wireless hand-held terminals that remotely control the RRPH, such as a Zenith Data Systems CruisePad™, for ease of use.

[0110] Upon entering the operating system 303, the program starts 306 at a main menu 307. The main menu 307 is referred to as a jump screen shown in FIG. 14A. At the jump screen 500, the operator can select from several options including: entering a new prescription 308, refilling a prescription 310, entering new patient information 311, generating reports 312, performing maintenance functions 315, or exiting the system 313. Each selection requires the operator to enter a password 309A-309E. The password function 309A-309E provides an appropriate level of security for each task. For example, generating a new prescription 308 may require a high level of security, for example, the pharmacist, while generating a report 312, may require a lower level of security, for example, a technician.

[0111] The password gate task 309 is shown in FIG. 13B. Initially, the user is prompted to enter a user ID and password 318 which is checked against a database 319 of user IDs, passwords, and security levels. The screen for entering the username and password is shown in FIG. 14Q. If the user ID and password are verified 320, then the operator is permitted to proceed and the system is returned 322 to the operation where the password task was initially called. Otherwise, a login attempt is recorded 321 and the user is prompted again to enter his password 318. Security measures may be installed to prevent break-ins. For example, when a predetermined number of invalid login attempts 321 are recorded, the system may be disabled for a period of time.

[0112] Returning to FIG. 13A, if the option to enter a new prescription 308 is selected and a proper password is entered 309A, then the operator is presented with a menu of selections shown in FIG. 14B. The menu is generated using a tab metaphor representing a plurality of files for the user to "thumb" through using the mouse. The tab selections include patient information 323A, payment 323B, drug 323C, signa 323D, patient medical profile 323E, and data verification 323F. In the patient window 323A shown in FIG. 14B, the operator is prompted to enter fundamental data concerning the patient including name, address, phone numbers, age, sex, weight, identification numbers, basic health information, and employer information. Alternatively, the operator may use the drop-down box 529 to select the patient name from a list. In which case the relevant data will automatically appear in the data windows.

[0113] Upon entering the above data, the operator next selects the payor and prescriber window 323B shown in FIG. 14C. In this window, the operator is prompted to enter information about the prescribing physician 501, the responsible pharmacist 502, and the person or insurance company responsible for payment 503. Pull-down menus indicated by arrows 504A, 504B are provided to allow the operator to select from a plurality of prescribers and pharmacists previously entered

into the database. Upon selecting a prescribing physician from the pop-down menu 504A, the relevant data 501 will automatically appear in the data windows. This patient data can be required before an enabling command can be sent to the controller and/or printer to dispense the desired item or print the necessary labeling and/or patient instruction printout.

[0114] In the drug window 323C, shown in FIG. 14D, the operator is prompted to select from a pop-down menu 505 of drugs available in the RCD units. When a drug is selected, the generic name, brand name, and NDC number of the drug available in the RCD unit automatically appears in the window, along with the quantity of doses in each bottle. At this time, the operator is afforded an opportunity to select a generic substitution 506, as opposed to a brand name drug. A generic substitution generally saves money for the patient and tends to be a more current formula for the drug. Label data to be printed upon dispensing is automatically updated by the software to include the generic drug information. In addition, the software automatically maintains an inventory and keeps track of the drugs which have been dispensed and assures a first-in-first-out inventory process. This provides a round-robin dispensing system so that drugs are continually circulated and therefore, expiration dates will pass less frequently. In addition, this system averages out solenoid use for each column in the cabinet such that one column does not wear more quickly than other columns in the cabinet. The drug window 323C also requires the operator to select an ICD-9 disease code from a pop-down menu 507. The ICD-9 code is an industry standard code number for a variety of ailments known to physicians.

[0115] Returning to FIG. 13C, upon entering the required data in the patient 323A, payor and prescriber 323B and drug 323C windows, the operator selects the signa window 323D. In the signa selection task shown in FIG. 13D, corresponding to window FIG. 14E, the operator is prompted to enter a signa by code 328, by text look up, or manually 330. Signa codes are industry standard acronyms or codes used by pharmacists for providing instructions to the patient. If the operator enters a code 328, then the software determines whether the code is in the database 331 and whether it has been used before 332 in the system. If not, the computer is instructed to learn the new code 333 by adding it to the database 334. In addition, the computer questions whether the signa dosage amount is correct for the new signa, as shown in FIG. 14S. The newly learned code is then available to the non-technical user via the Signa by Text option 329. In this way, the commonly-used Signa combinations of a facility (i.e. regimen) are learned and more readily available. The properties of the signa code include 335 include the number of units per day, the day's supply, the daily dosage, and the refill date. These properties automatically determined by the software after the operator enters the signacode. Following this, the software returns to the point where the

signa selection was called (see FIG. 13C).

[0116] In the profile window 323E shown in FIG. 14F, a menu of sub-files are available to the operator for selecting various patient medical data including refill information 508, allergy information 509, disease information 510, and medication history 511. In the allergy window 509 shown in FIG. 14F, a patient allergy table 512 includes a list of known allergies for the patient. The patient allergies 512 are selected from a master allergy table 513 which includes all known pharmaceutical allergies. The operator scrolls through the master allergy list and selects the appropriate allergy. Using the drag-and-drop method, the allergy is copied from the master allergy table to the patient allergy table 512. The allergy information is used during the drug utilization review (DUR) to determine if there is a conflict between the patient's allergy history and the prescribed pharmaceutical or any pharmaceutical in the patient profile. In FIG. 14G, the patient's disease history is tracked in a similar manner. A disease history for the patient 515, is selected from a master disease table 514. In FIG. 14H, a medication history for the patient is tracked. The data tracked includes active medications 516 and inactive medications 517, including the date that the medication was dispensed, the brand name, and source of the pharmaceutical. Again, the tracked medications 516,517 are selected from a master medication window 518. The data includes the National Drug Code (NDC) for all prescriptions.

[0117] In the verify window 323F shown in FIG. 14K, the operator is given an opportunity to view all relevant prescription data. The data includes a synopsis of the patient information, payor, prescriber, ICD-9, drug, signa, and adjudication information. At this point 325 (see FIG. 13C), the software verifies that all relevant data has been captured. If it has not, the operator is prompted to enter those portions of the data which are missing. Upon verification, the continue button 519 is enabled. This is indicated by darkening of the letters which spell out the word "continue" and by the button 519 flashing when ready. If any information is missing, the computer directs the operator to the appropriate window for entering the missing information.

[0118] When the continue button 519 (see FIG. 14K) is selected by the user 327 (DUR), the software performs a drug utilization review 337 as shown in FIG. 13E. During a drug utilization review, the software analyzes the patient profile 336 compiled by the operator and performs a plurality of tests 337 to check for drug conflicts. The tests include: drug allergy, drug disease, drug interaction, dose check, duplicate therapy, drug food, pediatrics, geriatrics, pregnancy, lactation, disease additive, drug additive, drug induced, polypharmacy, side effects, and other standard DUR tests. Note that this process need not be sequential as shown in FIG. 14K. Threads may be used to obtain simultaneous occurrences of each test. In this manner, the patient profile can be simultaneously tested in the DUR to arrive at re-

sults faster.

[0119] With reference to FIG. 13F, after a DUR test is completed, the user is provided with a drug utilization review window, as shown in FIG. 14I including a menu of tabs representing the various tests conducted. The DUR results are displayed as a series of tabbed folders of various colors as shown in FIG. 14I. Red folders 523, for example the "Lactation" folder of FIG. 14I, indicates a conflict with requires an override by the pharmacist. A red drug interaction field or has an additional feature of displaying a Drug Information Facts monograph for the user as shown in FIG. 14O. The user can additionally print the monograph for consultation with the responsible dispenser. In this manner on-line Drug Information is available for each drug interaction. A yellow folder 522, for example the "Duplicate Therapy" and "Drug Additive" folder, indicates that the tests should be checked by the pharmacist but does not require an override. A green folder, for example the "Geriatrics" folder 521, indicates that the tests passed without a conflict.

[0120] Returning to FIG. 13F, if the operator has selected a folder which is tabbed red, then the override button 520 is enabled 342 to allow the operator to override the flagged conflict. If no red tabs 339 are generated by the test, then the continue button 519 is enabled 340. When the continue button is selected 343 by the operator, the operator is prompted to enter a payment method 346. The payment method is selected in payor window 503 of FIG. 14C to determine which path to follow. If cash is selected, then a dispense subroutine is issued 377. If a third party payor is selected, then adjudication or payment confirmation takes place 347. The dispense and adjudication processes will be described below.

[0121] When the override command is selected 344, an override task 345 is called as shown in FIG. 13G. If the user is not authorized 349 to override the conflict, then a warning is displayed 358 and a remote or local pharmacist 359 is consulted. If a remote pharmacist is selected, the remote pharmacists key 361 is displayed and a connection is established 364 with encrypted data during the data exchange 367. Next, the computer performs an out dial to the remote pharmacist 368 who is given control of the dispensing process. As shown in FIG. 14V, during an override, the remote pharmacist will be required to enter a comment for dispensing to proceed.

[0122] If a local pharmacist is selected 359, the authorized pharmacist is prompted for a password 360. If several invalid attempts are recorded 363, then the override is ended and the dispensing will not be allowed to take place. If the pharmacist password is authorized 362, or if the user is authorized 349, the an override window shown in FIG. 14L is presented to the operator. The override window identifies the operator and the conflict to be overridden 350. The user is prompted to enter a justification for the override and will not be allowed to leave this override screen without entering a comment in the comment window 525. After the appropriate data

is entered, the data is captured to the database 355 by the operator clicking on the save button 526 and the program returns to the drug utilization review window shown in FIG. 14I. At this point, the previously red folder 523 will be given a new color, for example grey, to indicate that the conflict has been overridden.

[0123] During an adjudication process shown in FIG. 13H, a data packet is initially prepared 369 and the modem is initialized 370 as shown in FIG. 14P. After initial handshaking 371, a determination is made whether transmission 372 is enabled. If transmission is not yet cleared, then the software waits for a predetermined period of time 373, and if a time out occurs 374, then the transaction is saved to disk for later use 376 so that the data does not have to be reentered and the pharmaceutical is dispensed 377. If transmission has been cleared 372, then data is transmitted 375 and the process waits for a response 378. If after a predetermined period of time 379, the software determines that it has waited too long 380, then the transaction is saved to the disk for later use 381 and the pharmaceutical is dispensed.

[0124] When a response is received 378, the returned data packet is parsed 383 as shown in FIG. 13I. If the payor has not authorized the transaction 384, then a rejection is displayed on the monitor 393 and the operator is queried to cancel 388, save the transaction for later 389, or resend the transaction 390 as shown in FIG. 14V. If cancel 388 is chosen, then the program ends and returns to the jump screen 500 shown in FIG. 14A. If "save for later" 389 is selected, then the transaction is saved to the disk for later use 392 and a dispense command is ordered 377. If resend 390 is selected, then the operator is given an opportunity to modify the outbound data packet 391 and adjudication is initiated again. If the payor authorizes the transaction 384, then an approval is displayed on the monitor 385 and the operator is queried whether he accepts the approval 386. If so, and the operator has to respond to a payor DUR 387, then adjudication is performed again. Otherwise, a dispense task 377 is performed.

[0125] With reference to FIG. 13J, in a dispense task 377 the transaction is initially recorded in a transaction database 394 and a drop signal is sent to the dispenser 395. Upon receiving feedback from the dispenser 396, two barcoding safety options are possible 397. Under the first option, the barcode on the dispensed bottle is scanned 404 after a prompt by the software as shown in FIG. 14M. The prompt 528 requests the operator to scan the barcode label. After scanning, if the barcode matches that which the computer expects 405, then a patient monograph and bottle label is generated as shown in FIG. 15. The computer next prompts the user to report that the label has been applied to the bottle as shown in FIG. 14R.

[0126] The barcode applied to the dispensed package by the repackager may contain expiration date information which the computer automatically checks upon scanning the barcode. If the package has expired, the

operator may be warned, and the label and monograph print function disabled. Also, the computer may check the package date against the ending date of the prescription period and disable the print function or otherwise warn the operator if this test fails.

5 [0127] Alternatively, if the second barcoding safety option is selected 397, then the printout is generated initially 398 and labels and safety barcodes from the printout are adhered to the bottle 399. The repackager 10 barcode on the bottle and a prescription generated barcode are optically read or scanned 400 and the computer electronically compares the two codes to determine if they match 401.

[0128] Returning to FIG. 13J, if the bar codes fail to 15 match 402, 403, then all data responsible for generating the error is captured 417 as shown in FIG. 13L and a warning is issued to the operator that the pharmaceutical or other item is not cleared for dispensing 418. Potential corrective measures are displayed 419, and the operator is given the option to lock the column generating the error 420. If so, the operator instructs the computer to lock the column 421. The server is automatically notified 422 by the computer via modem 423. After the server acknowledges receipt of the error 424, the program returns to the point where the dispense task was 20 called.

[0129] With reference to FIG. 13K, if a proper dispensing has occurred, then the transaction is recorded to the 25 data base 407, and the computer determines whether inventory is at or below a predetermined restock value 408. If the inventory is at an appropriate value, the program returns to where the dispense task was called. Otherwise, an encryption program is activated 409 and an outdial to the server headquarters is performed 410

30 via modem 411. If the server acknowledges 412, then the files are marked as sent 413 and the software returns to the point where the dispense task was called. If the server fails to acknowledge within a limited number of attempts 414, then the operator is warned 415 that a 35 communication problem exists and a command to start a timer for periodic low-inventory-dial-outs or "LIDOS" is initiated 416. A LIDO is a parallel background process for calling the distribution headquarter to replenish inventory. Following this, the computer returns to the point 40 where the dispense task was called. In addition to the 45 automated inventory processes described above, an operator may at any time monitor inventory in an RCD unit by selecting the "Inventory" option shown in FIG. 14T. This image shows the number of bottles in each RCD bin or column.

[0130] During an override procedure shown in FIG. 50 13G, if a connection to a remote pharmacist 364 is established, at the remote pharmacist workstation as shown in FIG. 13M, the data received is decrypted 428, and the computer determines whether a share or package exchange 427 is occurring. In the case of a share exchange, the remote pharmacist assumes control of the system 429 and a remote pharmacist password is

generated 426. In the case of a packet exchange 427, the data is displayed 425, and the remote pharmacist password is generated 426.

[0131] FIG. 13N is a flow diagram representing remote pharmacist password generation 426. Initially, a display key is transmitted from the remote system 431. The key is entered into the local program 432 and the local program decodes the key and generates a counter key 433. This counter-key is used as the remote pharmacists password 434. At this point, the program returns to the point where the remote pharmacist password generation task 426 was called. With reference to FIG. 13O, if the refill option 310 is selected at jump screen 500 shown in FIG. 14A, then all relevant data should have already been entered into the database. At this point, the patient's name is selected 435 and a refill is selected for the patient 436. After a payment method is selected 437, a drug utilization review is performed, along with adjudication and dispensing as described above.

[0132] FIG. 13P is a flow diagram representing tasks performed when the new patient 311 option is selected at the jump screen. In this task, new patient demographics 438, allergy profile 439, disease profile 440, and medical profiles 441 are entered for the new patient. After this task is performed, control is returned to the jump screen of FIG. 14A.

[0133] With reference to FIG. 13Q, if the reports option 312 is selected at the jump screen, a list of available reports are presented to the operator. The operator is given a choice to print or preview a report 443. If the preview option is selected, then the report is generated on the monitor 444. After viewing the report 444, the operator is given a choice whether to print the report 445, and if so, the report is sent to the printer 446.

[0134] FIG. 16 is a schematic diagram representing a typical remote drug dispensing configuration in accordance with the present invention. System access locations are shown in a first city 550, second city 551, and a third city 552. Pharmacists and physicians in the second 551 and third 552 cities communicate with physicians, pharmacists, and technicians in the first city 550 via telephone connections 553, for example, a telephone modem, or an ISDN connection. A gateway computer 555 in the first city 550 operates as a server to receive and transmit messages on the telephone lines 553. Access stations in the first city 550 are interconnected via an intranet 554 otherwise known as an ethernet or local area network (LAN). The LAN may be located in a hospital, an HMO, or a pharmacy. Hardware connected to the LAN 554 includes the gateway workstation 555, a laptop computer 566 with video teleconferencing capabilities 567, a pen computer 568, a facsimile 557, and an RCD host computer 564 operating an RCD unit 556. The RCD host computer 564 may also have video teleconferencing hardware 563 and a plurality of pen computers 565 connected thereto.

[0135] When a patient approaches a technician at an RCD unit 556, the technician initiates the dispensing

process by entering relevant patient data into the RCT host computer 564. If the dispensing process requires the expertise of a pharmacists, then the technician at the host computer 564 issues a request to an available 5 pharmacist operating the pen computer 568, laptop computer 566, or workstation 555 within the building in the first city 550, or may request the services of a pharmacist operating an RPH workstation 559 in the third city 552 or a pharmacist at the laptop computer 561 in the second city 551. Relevant data is exchanged and 10 video teleconferencing is enabled between the technician and the pharmacist or prescribing physician if appropriate. Hand written scripts may be transferred to and from the first city 550 via facsimile 557. The facsimile 15 image may be downloaded into the host computer 564 and stored with relevant patient data.

[0136] FIG. 17 is a schematic block diagram representing the transfer of data between an RCD host computer 570 and a remote RPH workstation 571. A technician at the host computer 570 receives a request for 20 a prescription from a patient at the RCD unit 572. The technician prepares the relevant data including the patient record, the prescription to be dispensed, and the adjudication information. The data is packed, encrypted and transmitted over the internet 573 to the RPH workstation 571 operated by a registered pharmacist. The pharmacist receives the data, conducts the relevant 25 tests and makes a determination regarding dispensing the pharmaceutical. A packet of data is prepared with the patient's records, data, and any comments, along 30 with a signal to cause the RCD unit 572 to dispense. This data packet is transmitted over the Internet 573 as an Email message or other data file to the host computer 570. The host computer 570 receives the message, unpacks the data, and dispenses the pharmaceutical automatically, in real time. In this manner, a pharmacist operating a remote workstation 571 causes the RCD unit 572 to dispense the pharmaceutical in real time. Alternatively, the dispense commands may be issued in a 35 batch process, requiring the technician at the host computer 570 to issue the dispense command to the RCD unit. Scripts from the host computer 570 generated by the technician may also be transmitted to the pharmacist at the RPH workstation 571 in batch form.

[0137] FIG. 18 is a schematic block diagram representing connectivity between RCD units at various sites. For example, a hospital site 575, may communicate with an HMO 576 via the internet 579. At the hospital site 575, two RCD units 581A, 581B are supported by two 40 RCD host computers 580A, 580B respectively. The host computers communicate via Intranet 578A, otherwise known as an internal internet, or a LAN. A server 584 on the LAN 578A provides an interface between the LAN 578A and the internet 579. The RCD units 581A, 581B 45 may serve two separate wards in the hospital. At the HMO office 576, a similar configuration employing two RCD units 582A, 582B hosted by host computers 583A, 583B are interconnected by a LAN 578B, and server 50

585. Distribution headquarters 577 also interfaces with the internet 579. In this manner, headquarters 577 can automatically keep track of stock levels, patient data, and other data warehousing functions.

[0138] FIG. 19 is a schematic block diagram representing dual modem configuration. An RCD host computer 585 serving an RCD unit 593 in a first city 586 is configured to operate with a first and second modems 594A, 594B. Using the first modem 594A, the technician at the host computer 585 may solicit instructions from a pharmacist in a second city 587 operating a RPH workstation 589, a pen computer 590, or a laptop computer 591 each equipped with a modem 592A-C. A second modem 594B on the RCD host computer 585, allows for adjudication to take place with an adjudication switch 590 in a third city 588 while the link between the RPH workstation 589 and the RCD host computer 585 is maintained. In this manner, a pharmacist at a remote location in a second city 587 can access an RCD host computer 585 through a first modem 594A and perform adjudication between the RCD host computer 585 and an adjudication switch 590 in a third city 588 using the second modem 594B.

[0139] Alternatively, if the remote pharmacist at the RPH workstation 589 did not wish to remain online during adjudication, then the remote pharmacist could issue an adjudication batch command to be performed by the RCD host computer 585. After the batch command is issued, the link between the RPH workstation 589 and the host computer 585 is deactivated and the host computer performs adjudication. After adjudication is completed, the RCD host computer 585 reestablishes the link between the RCD host computer 585 and the RPH workstation 589 to inform the remote pharmacist that adjudication is completed. This batch process requires only a single modem at the RCD host computer 585 which is time-shared for script and adjudication processing.

[0140] While this invention has been particularly shown and described with references to preferred embodiments thereof, it will be understood by those skilled in the art that various changes in form and details may be made therein without departing from the spirit and scope of the invention as defined by the appended claims.

[0141] In particular, embodiments of the invention may include the features of the following enumerated paragraphs ("paras").

1. A system for automated dispensing of a package comprising:

a controller for generating a dispense signal in response to a request signal;  
a housing having a plurality of bins, each bin storing an encoded plurality of packages, each of said bins having a dispenser coupled to said controller for dispensing a package therefrom

5 in response to said dispense signal; and a code reader coupled to said controller for reading the code of a dispensed package.

10 2. The system of para 1 wherein said bins comprise columns, said packages being gravity-fed in the columns.

15 3. The system of para 2 wherein the dispenser comprises a plurality of valves actuated by a corresponding plurality of solenoids, said solenoids being sequentially activated such that a single package is dispensed from a column per request.

20 4. The system of para 1 wherein said code reader comprises a bar code reader and the packages are encoded with bar codes.

25 5. The system of para 1 further comprising sensors coupled to said controller for monitoring inventory of said packages.

30 6. The system of para 1 wherein said code reader comprises a bar code reader and the packages are encoded with bar codes.

35 5. The system of para 1 further comprising sensors coupled to said controller for monitoring inventory of said packages.

6. The system of para 1 wherein said packages comprise bottles.

30 7. The system of para 1 further comprising a label printer for printing a prescription label for attaching to said dispensed package.

40 8. The system of para 7 wherein the printed prescription label includes a printed picture of a pharmaceutical contained in the dispensed package.

9. The system of para 1 wherein said housing is adapted for mounting on a wall.

45 10. The system of para 1 wherein the dispenser comprises a roller actuated by a motor.

11. The system of para 1 wherein the bins comprise drawers and the dispenser comprises a helix actuated by a motor.

50 12. The system of para 1 further comprising a ramp that delivers a dispensed pharmaceutical in the package to a drop point.

55 13. A method for dispensing packages comprising:  
storing a plurality of coded packages in a hous-

ing;  
reading the code of a package with a code reader;  
verifying that the requested package was dispensed; and further characterizing by  
receiving request signals at an electronic controller in the housing from a computer to dispense a package;  
generating dispense signals received by a dispenser associated with the requested package from the electronic controller in the housing in response to the received request signals;  
displaying package information on a computer display; and  
dispensing before the steps of reading the code of a package the package from the housing in response to the dispense signal.

14. The method of para 13 further comprising the step of printing a prescription label at a label printer for attaching to the dispensed package. 20

15. The method of para 14 further comprising the step of printing a picture of a pharmaceutical pill on the label. 25

16. The method of para 13 further comprising providing a plurality of multi-dose pills in each package.

17. The method of para 13 further comprising providing each packaged item in a plastic bottle. 30

18. The method of para 13 wherein the code of the dispensed package comprises a first code and further comprising the steps of:  
printing a second code pertaining to the contents of the dispensed package;  
optically reading the first and second codes; and  
verifying the package by comparing the first code and second code. 35

19. The method of para 18 further comprising displaying package information on a computer display and displaying an instruction not to deliver the package if the second code does not match the first code. 40

20. The method of para 13 further comprising the steps of:  
performing a plurality of required patient data entry operations; and  
automatically enabling or disabling the step of dispensing after completion of the patient data entry operations such that dispensing occurs only upon receipt by the controller of an ena- 45

bling command.

21. The method of para 20 further comprising providing an override command such that a user can enable the controller to dispense a package and recording an override command entry in a computer memory.

22. The method of para 20 further comprising color encoding displayed patient data files on the display.

**Claims**

1. A system for automated dispensing of packaged medical products comprising:  
a housing having a plurality of bins;  
a computer that controls dispensing of packaged medical products;  
a communication network connected to the computer;  
each bin storing a plurality of packaged medical products;  
an electronic controller within the housing that generates a dispense signal in response to a request signal from the computer, the computer receiving a dispense instruction through the communication network; and  
a dispenser associated with each bin within the housing that controls dispensing of packaged medical products within the bins such that a product is dispensed in response to the dispense instruction.
2. The system of claim 1 wherein said bins comprise columns, said packages being gravity-fed in the columns, and, optionally, wherein the dispenser comprises a plurality of valves actuated by a corresponding plurality of solenoids, said solenoids being sequentially activated such that a single package is dispensed from a column per request.
3. The system of claim 1 wherein said communication network comprises the Internet or a telephone network.
4. The system of claim 1 further comprising sensors coupled to said controller for monitoring inventory of said packages.
5. The system of claim 1 and either:
  - a) wherein said packages comprise bottles;
  - b) further comprising a label printer for printing a prescription label for attaching to said dispensed package, and, optionally, wherein the printed prescription label includes a printed pic-

ture of a pharmaceutical contained in the dispensed package;  
 c) wherein said housing is adapted for mounting on a wall;  
 d) wherein the dispenser comprises a roller actuated by a motor;  
 e) wherein the bins comprise drawers and the dispenser comprises a helix actuated by a motor;  
 f) further comprising a ramp that delivers a dispensed pharmaceutical in the package to a drop point;  
 g) wherein the communication network is connected to a server having a patient record database;  
 h) further comprising a video link through the communication network;  
 i) comprising a first camera connected to the computer and a second camera connected to a second computer that is connected to the network;  
 j) further comprising a pharmacy computer connected to the network;  
 k) further comprising a card reader; or  
 l) wherein the medical product comprises packaged pharmaceuticals. 5

6. A method for dispensing packages comprising:  
 storing a plurality of medical packages in a housing;  
 further characterized by delivering dispense instructions to a computer with a communication network;  
 receiving a request signal at an electronic controller in the housing from the computer to dispense a package;  
 generating dispense signals received by a dispenser associated with the requested package from the electronic controller in the housing in response to the received request signals; and dispensing the package from the housing in response to the dispense signal. 30

7. The method of claim 6 further comprising the step of printing a prescription label at a label printer for attaching to the dispensed package, and/or the step of printing a picture of a pharmaceutical pill on the label. 45

8. The method of claim 6 further comprising providing a plurality of multi-dose pills in each package. 50

9. The method of claim 6 further comprising providing each packaged item in a plastic bottle. 55

10. The method of claim 9, and either:  
 a) further comprising adjudicating payment for the package with the network;  
 b) further comprising displaying package information on a computer display and displaying an instruction not to deliver the package;  
 c) further comprising the steps of:  
 performing a plurality of required patient data entry operations; and automatically enabling or disabling the step of dispensing after completion of the patient data entry operations such that dispensing occurs only upon receipt by the controller of an enabling command, and, optionally, further comprising providing an override command such that a user can enable the controller to dispense a package and recording an override command entry in a computer memory;  
 d) further comprising color encoding displayed patient data files on a display connected to the computer;  
 e) further comprising connecting the computer to the Internet;  
 f) further comprising actuating a rotary dispenser that dispenses packages;  
 g) further comprising connecting the network to a server having patient data records;  
 h) further comprising connecting the computer to a pharmacy computer;  
 i) further comprising connecting a video camera to the computer and transmitting video with the network;  
 j) further comprising connecting the network to a local area network;  
 k) further comprising transmitting a data packet or electronic mail message over the network;  
 l) further comprising performing a drug utilization review before dispensing a packaged pharmaceutical;  
 m) further comprising printing a report associated with a dispensed package;  
 n) further comprising entering a password to access data via the network;  
 o) further comprising performing an inventory operation with the network;  
 p) further comprising transmitting barcode information over the network;  
 q) further comprising recording each dispensing operation in a memory;  
 r) further comprising programming a plurality of computers connected to the network with software module to perform separate dispensing operations;  
 s) wherein the computer and dispenser are positioned within a common housing, the dispenser including a rotary dispenser and a gravity fed

dispenser;  
i) further comprising a medication database on  
a server connected to the network;  
u) further comprising a windows operating sys-  
tem on the computer;  
v) further comprising securing the packages  
within a locked dispenser housing; or  
w) wherein the controller comprising a micro-  
processor, a serial port, a solenoid selector, a  
buffer, a clock, and a power bank.

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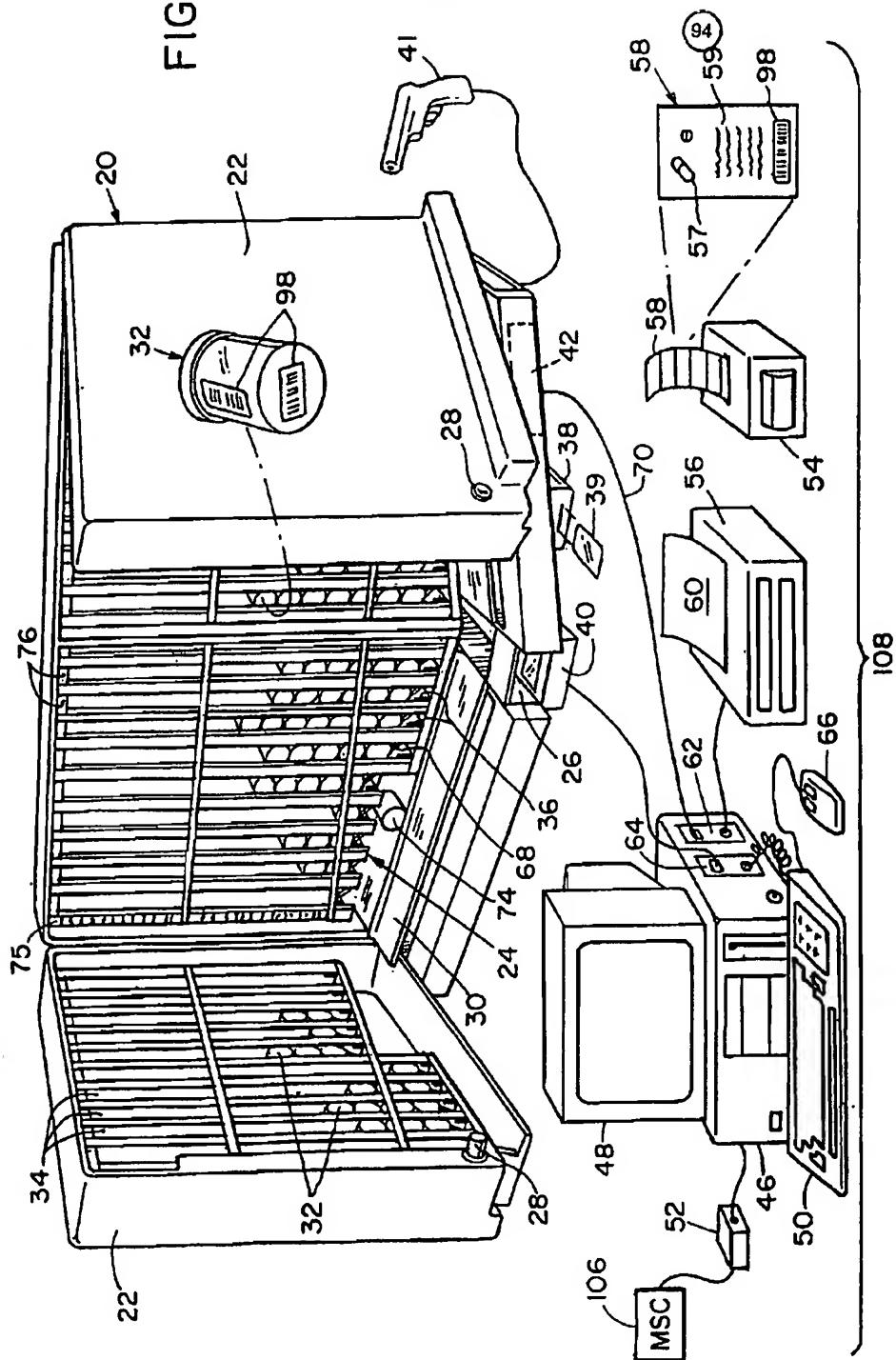
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50

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FIG. 1

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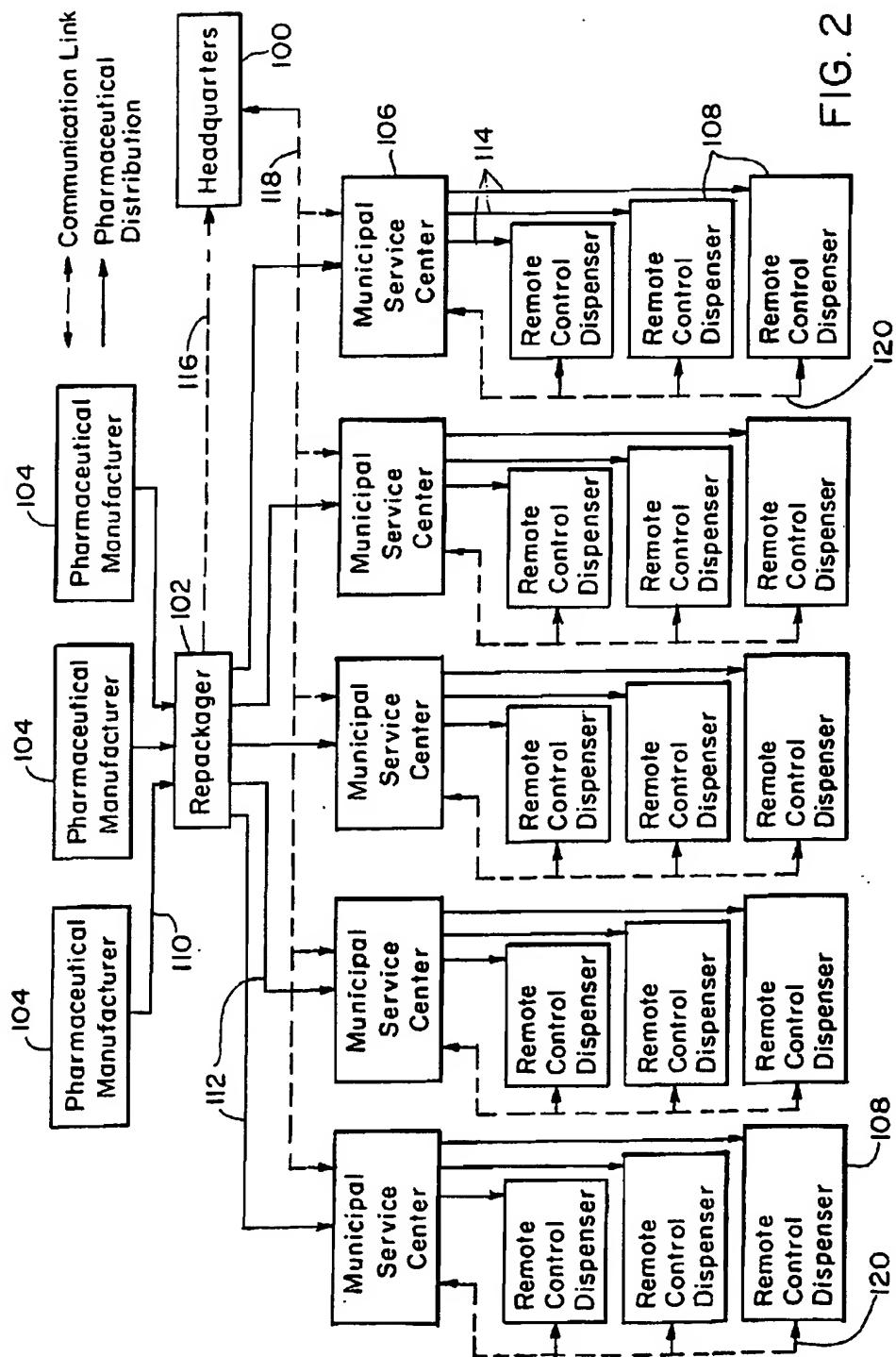


FIG. 2

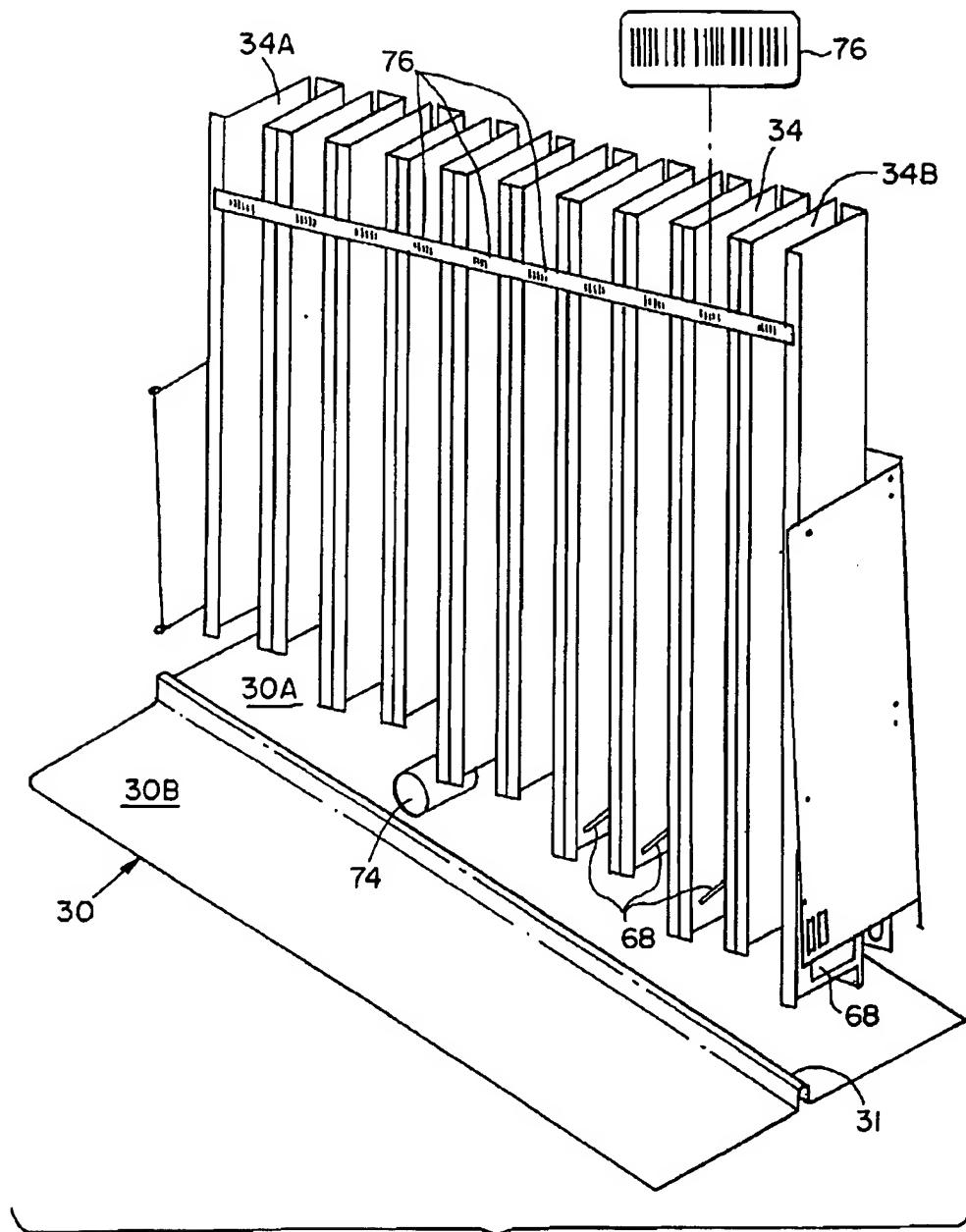


FIG. 3

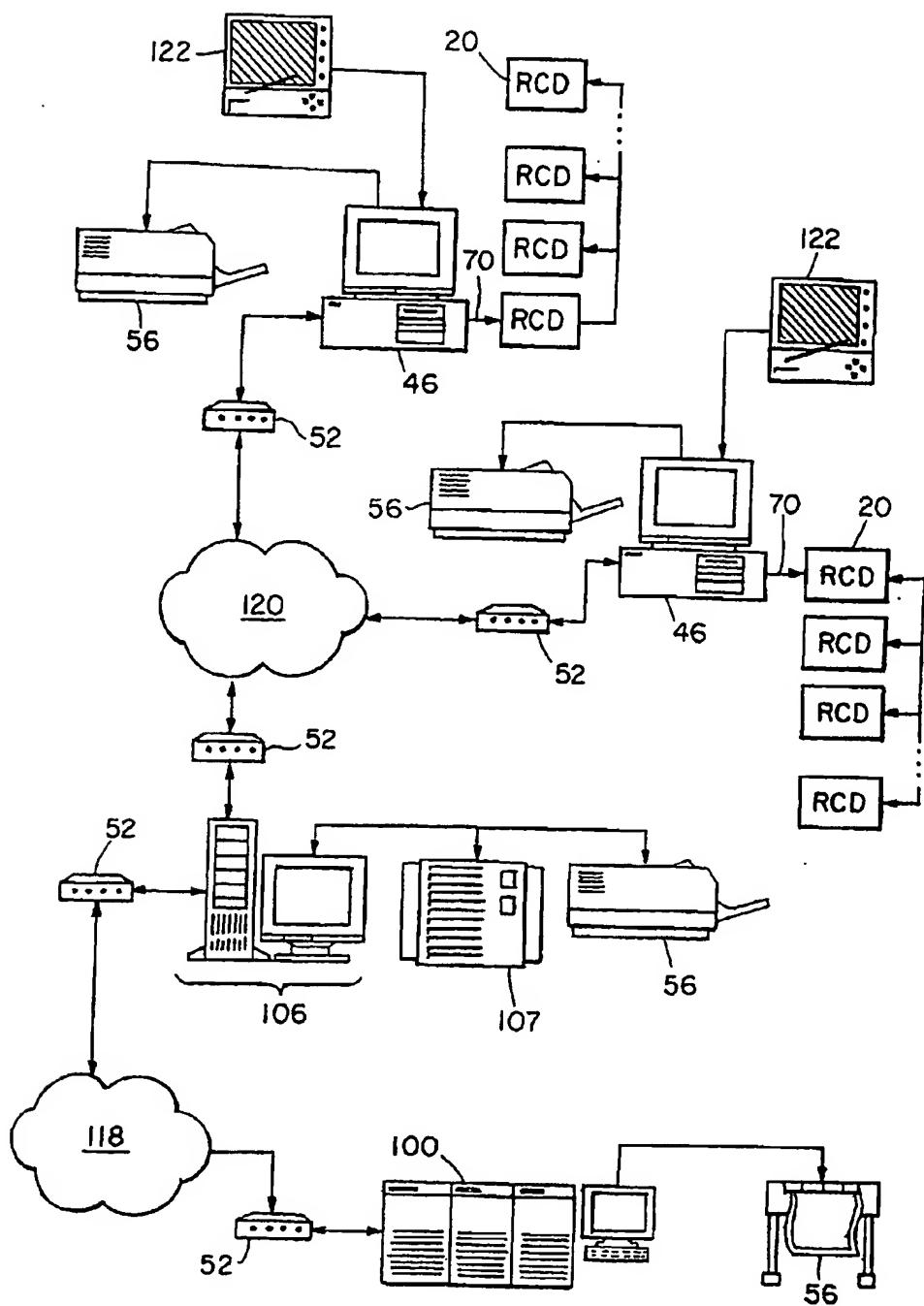


FIG. 4

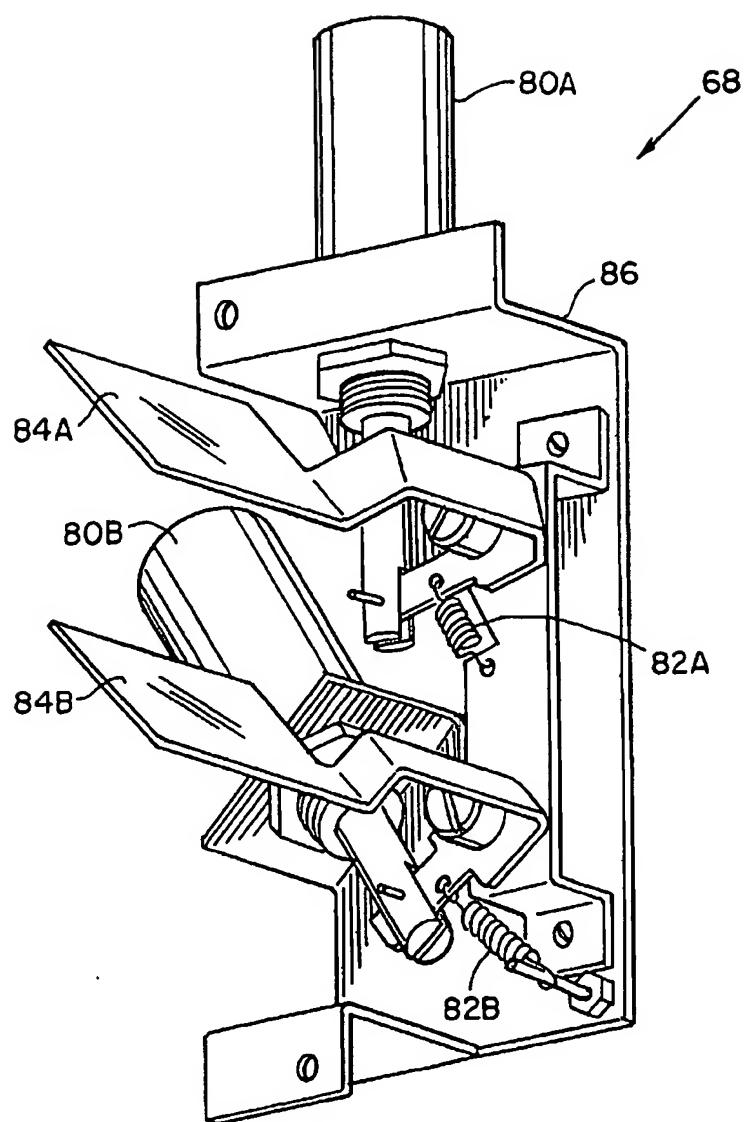


FIG. 5

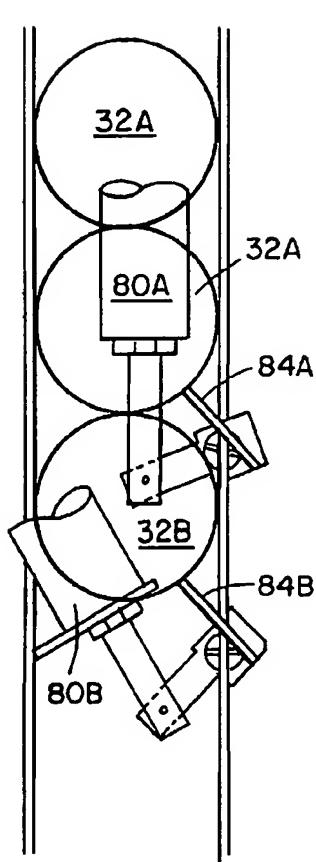


FIG. 6A

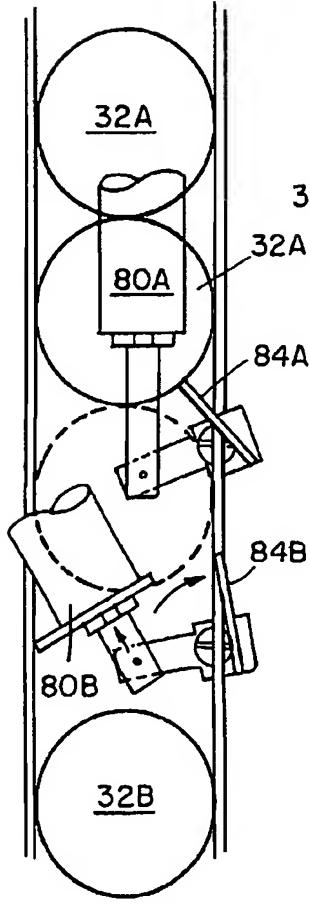


FIG. 6B

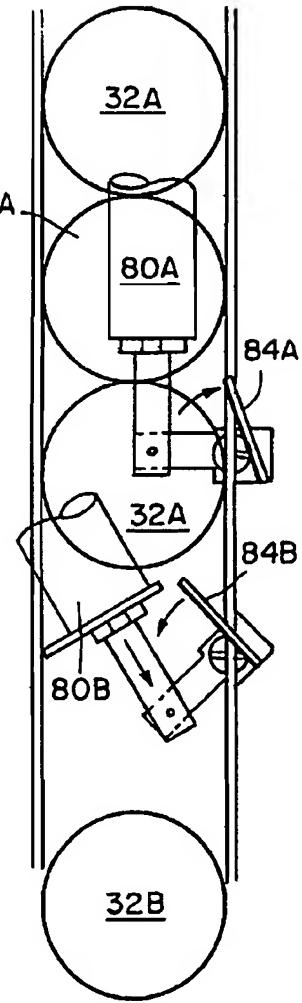


FIG. 6C

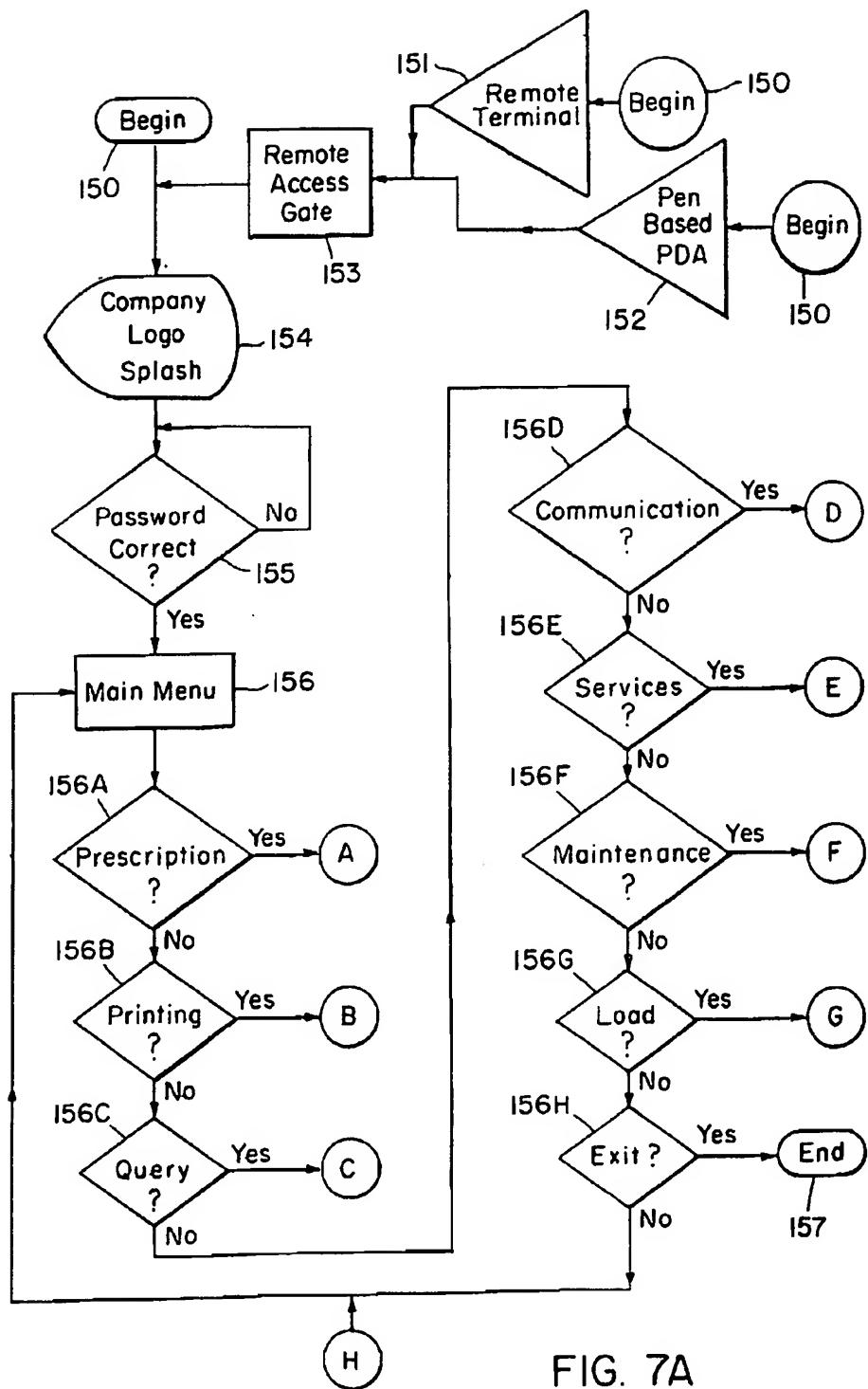


FIG. 7A

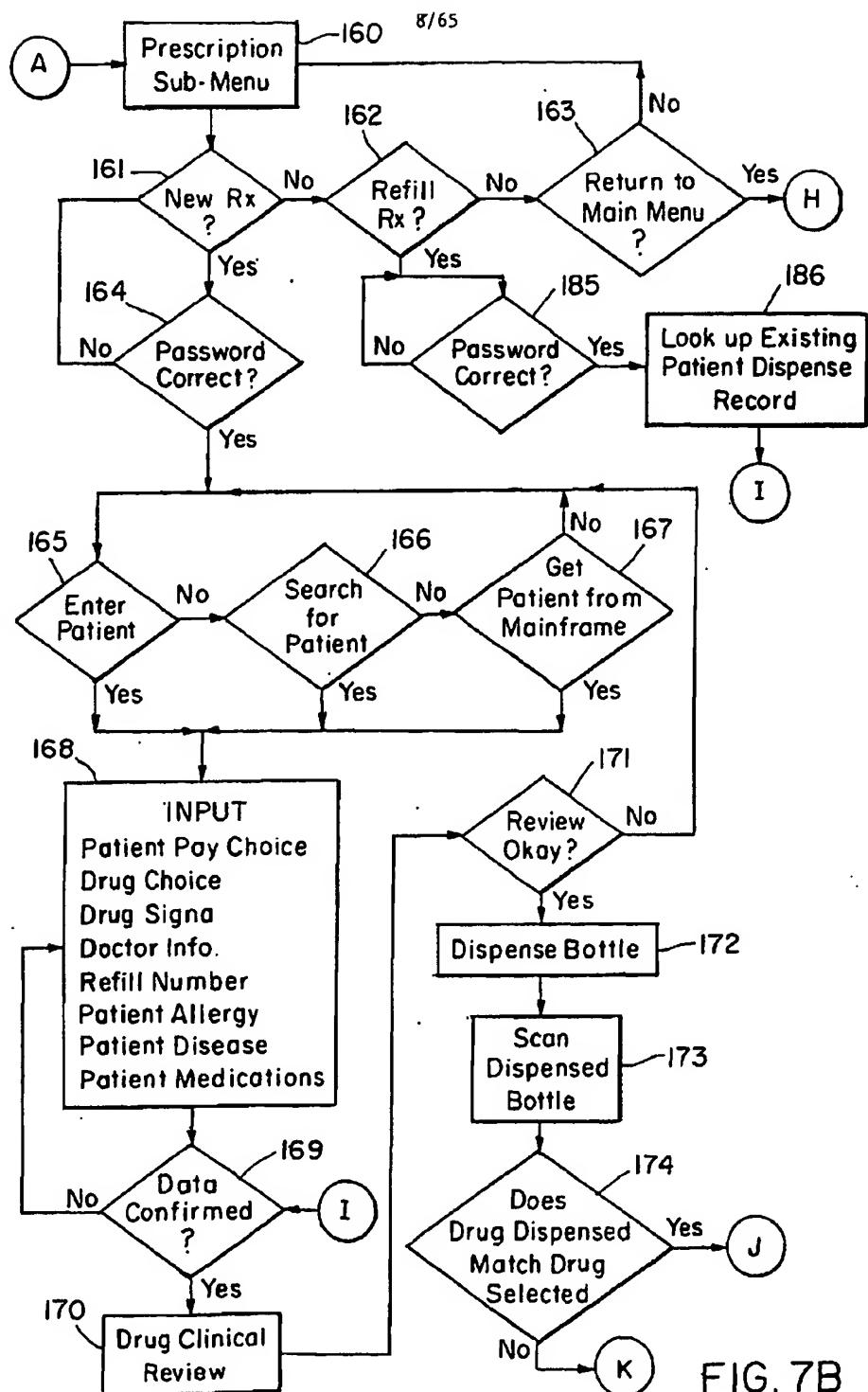


FIG. 7B

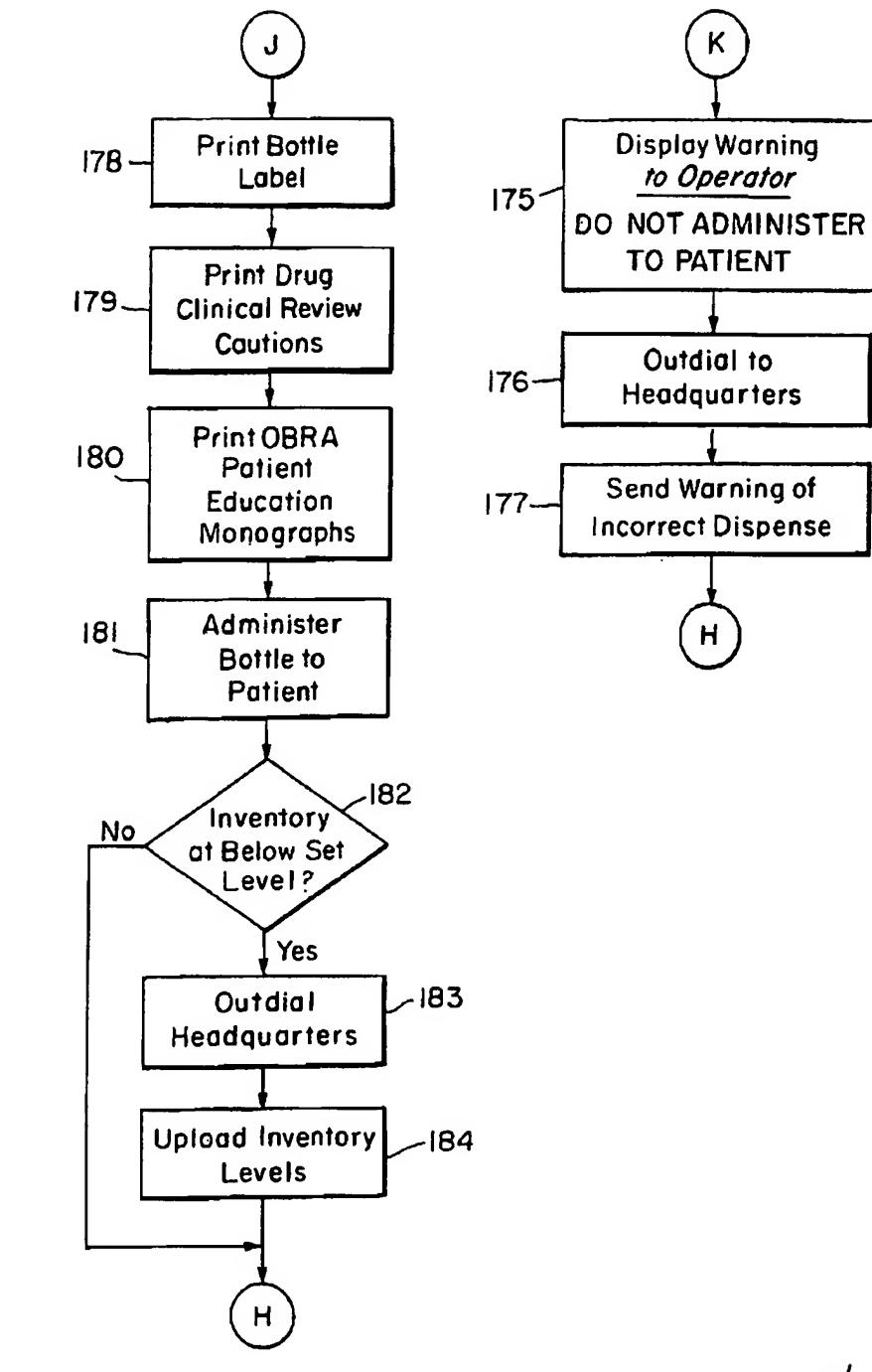


FIG. 7C

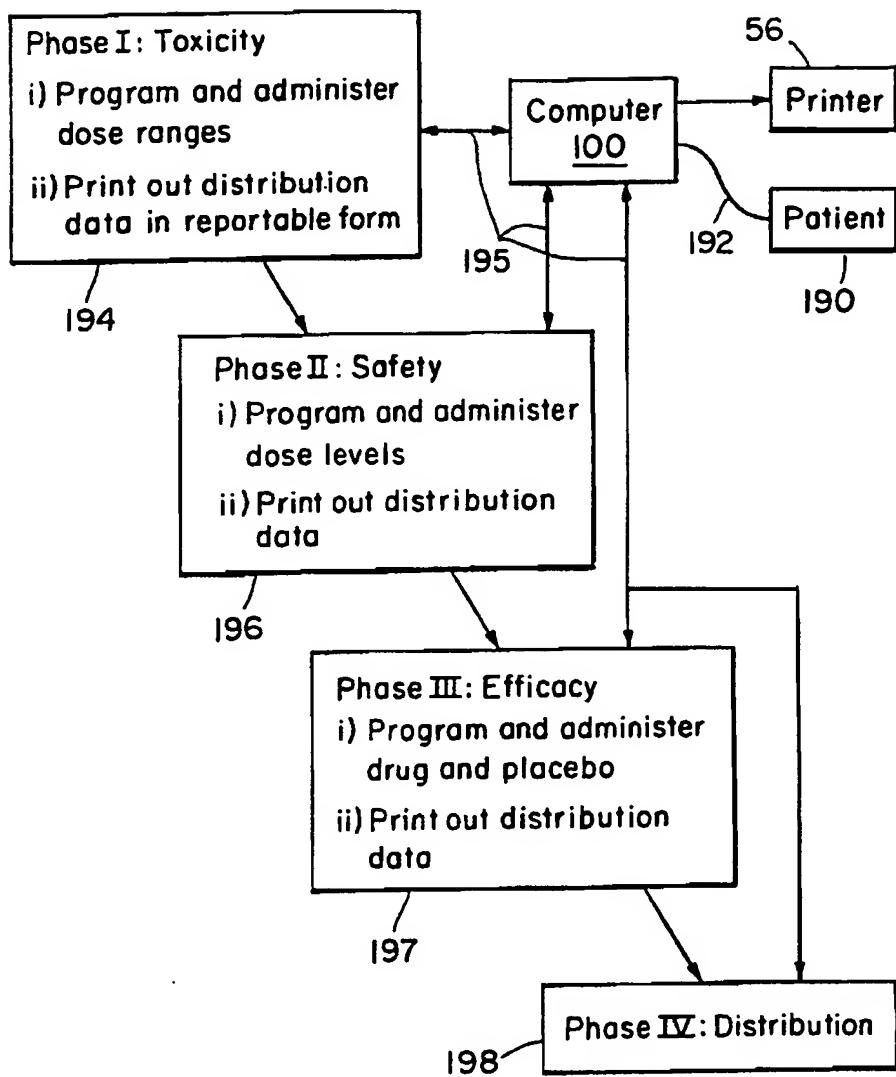


FIG. 8

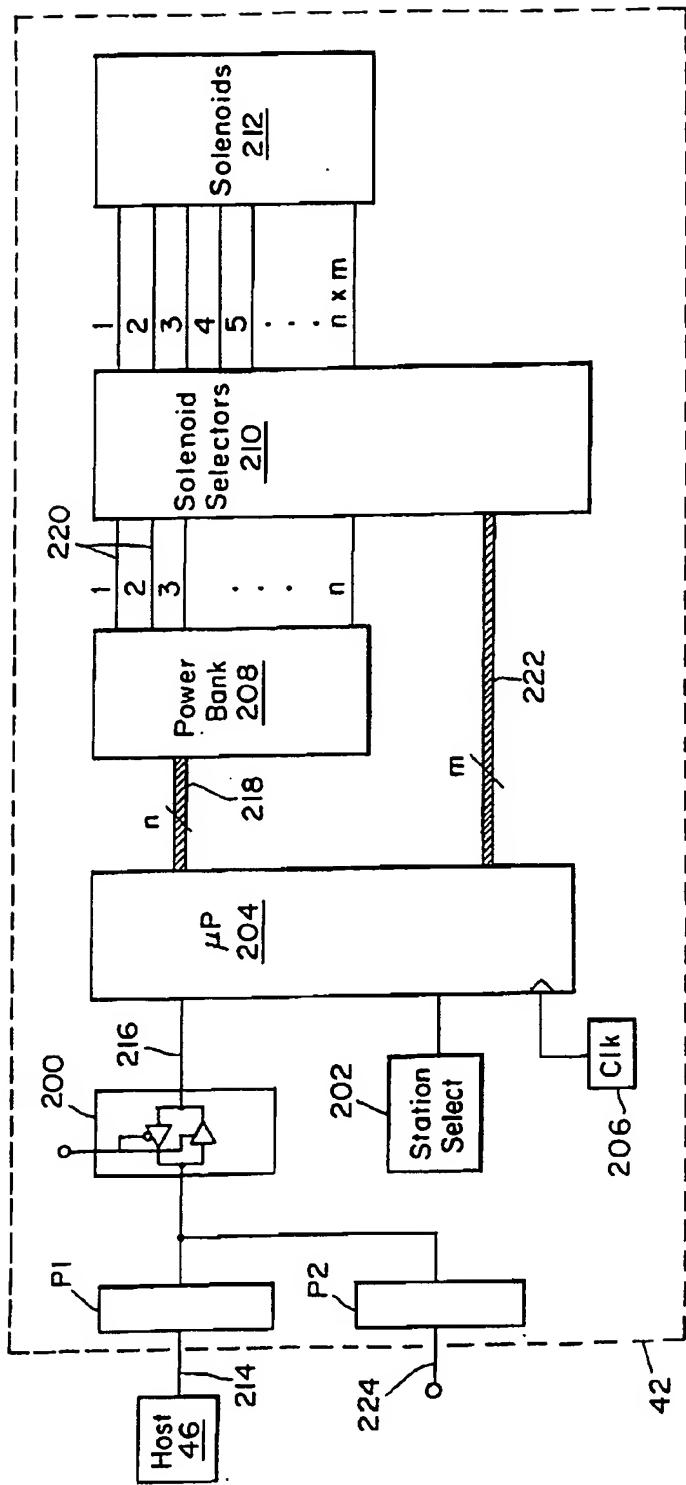


FIG. 9

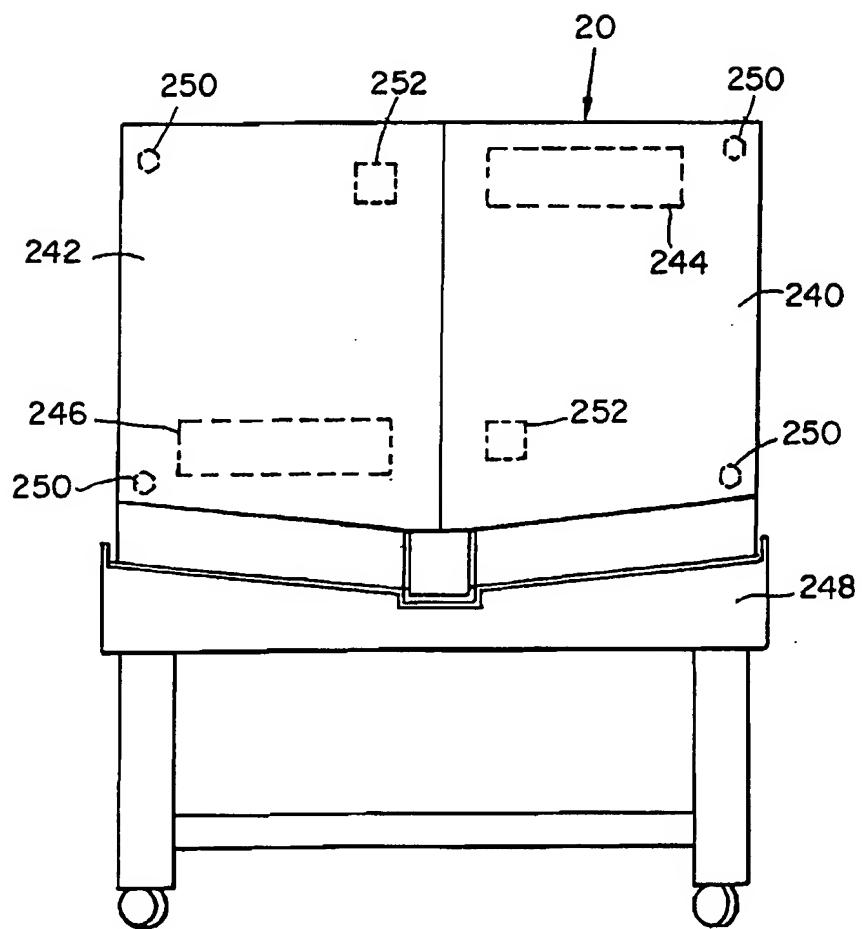


FIG. 10

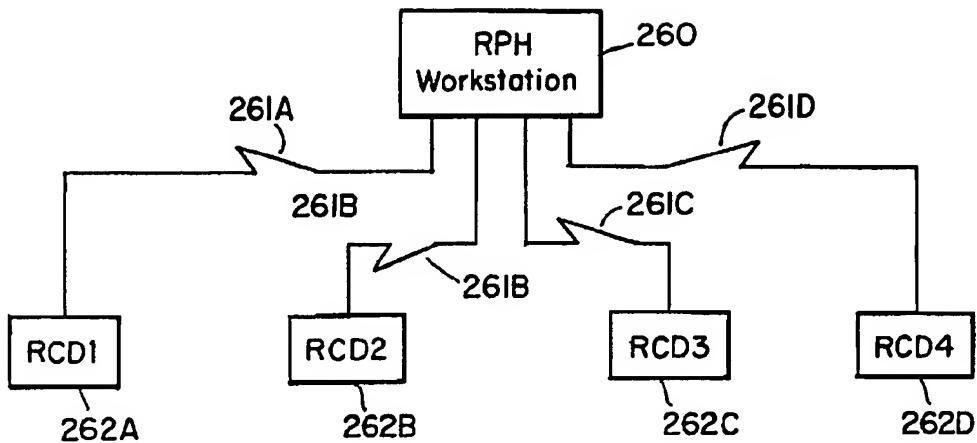


FIG. 11A

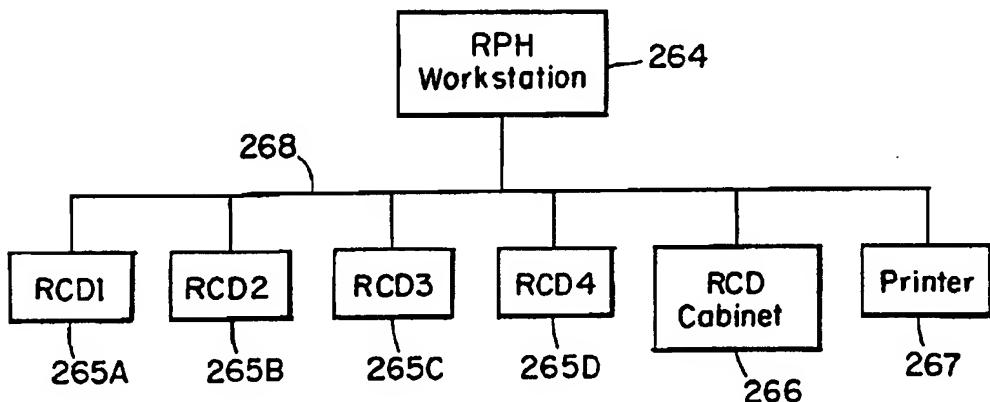


FIG. 11B

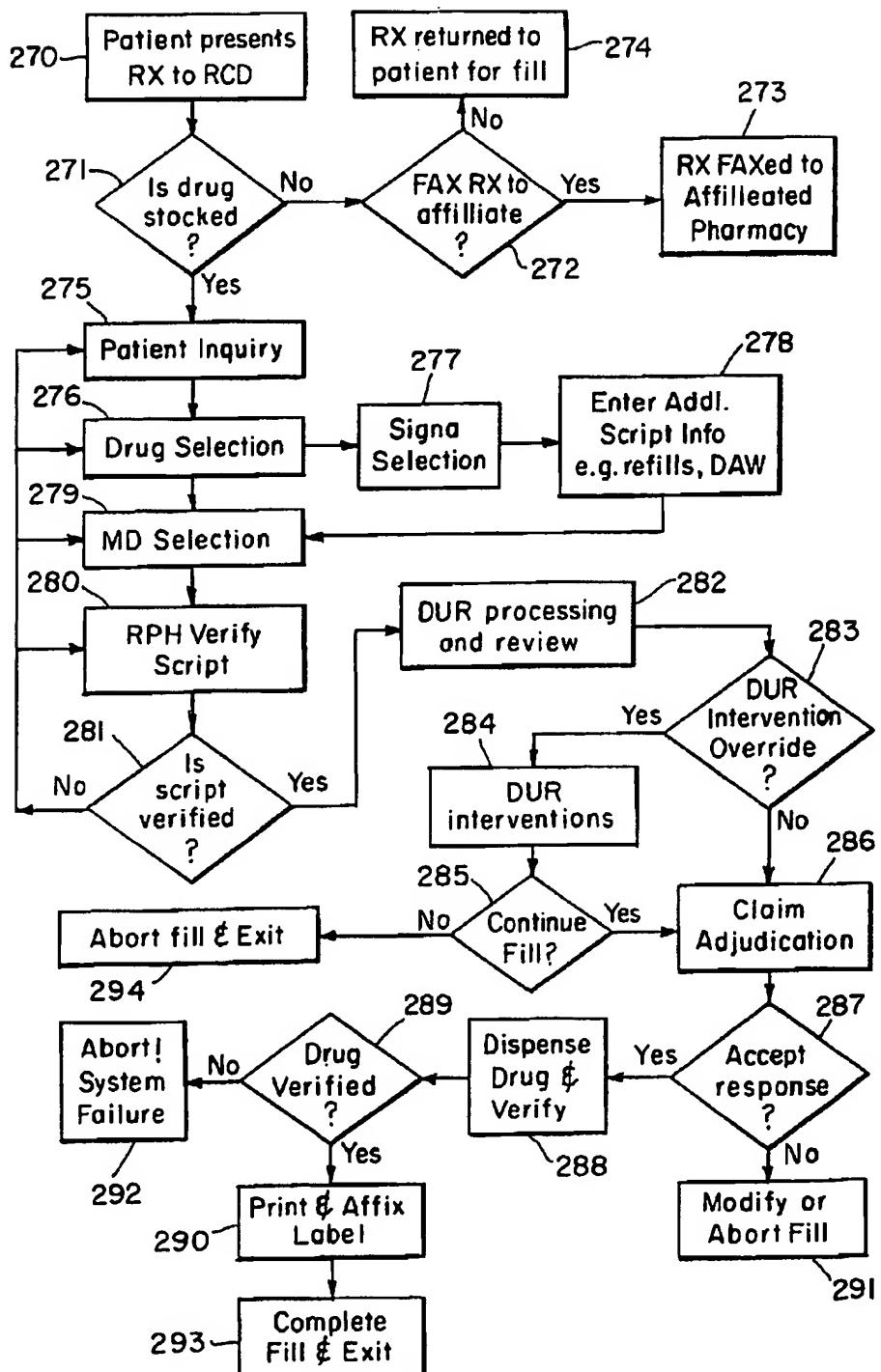


FIG. 12

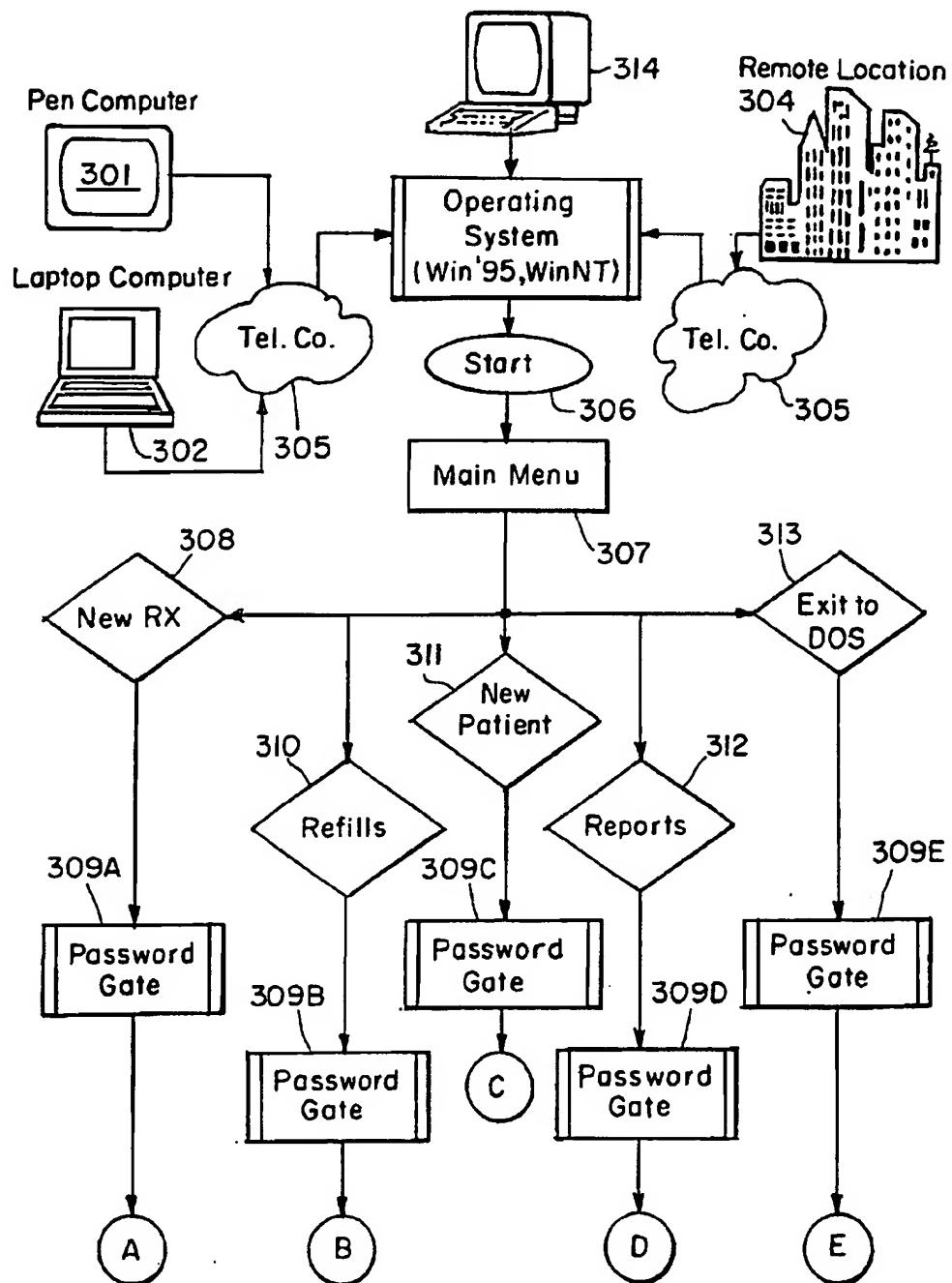


FIG.13A

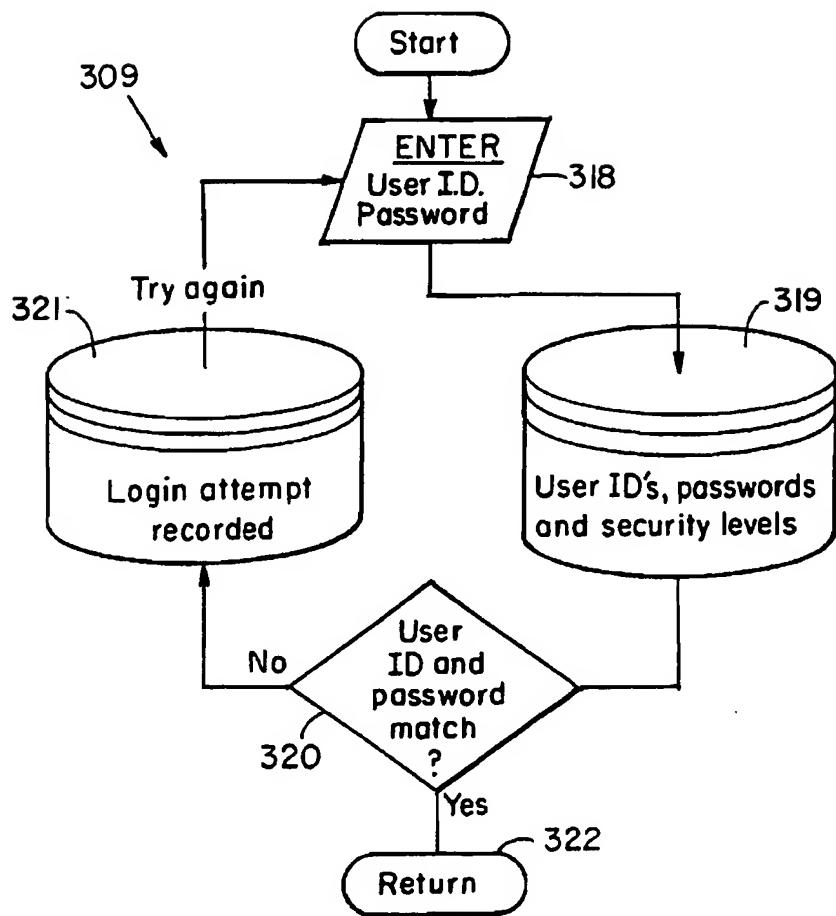


FIG. 13B

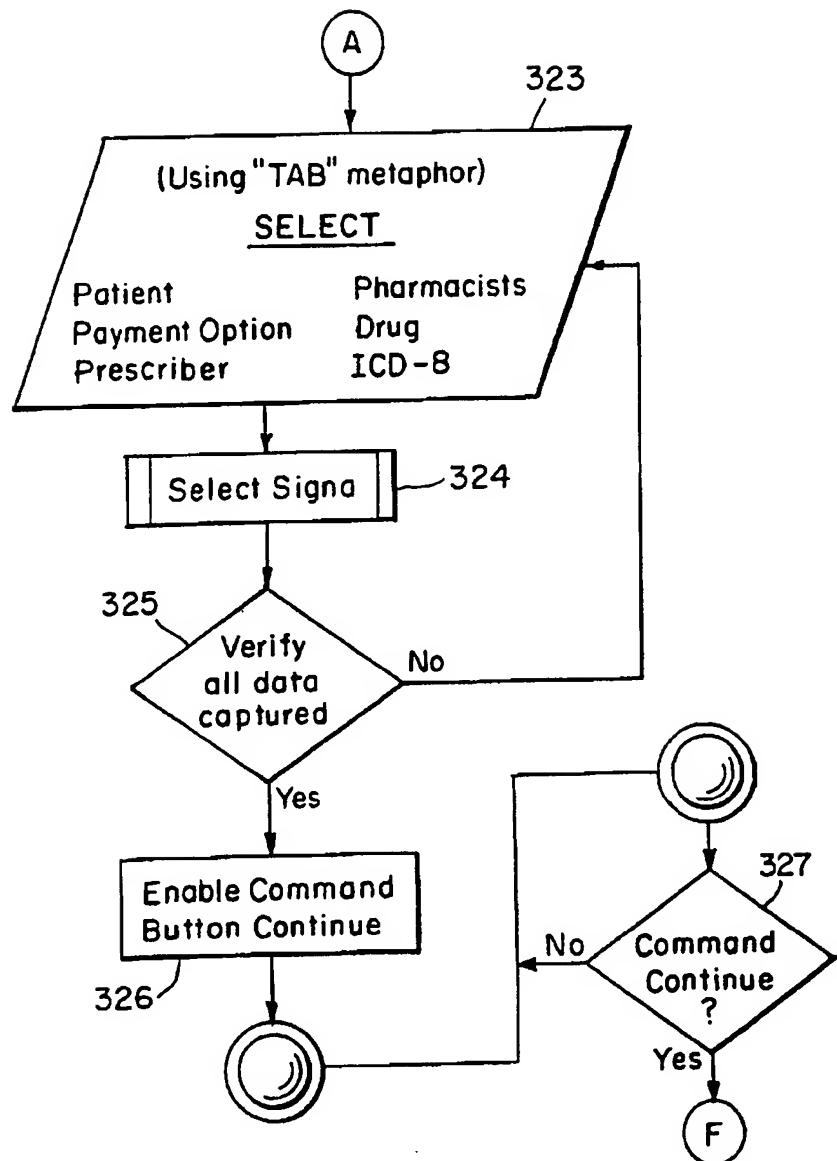


FIG. 13C

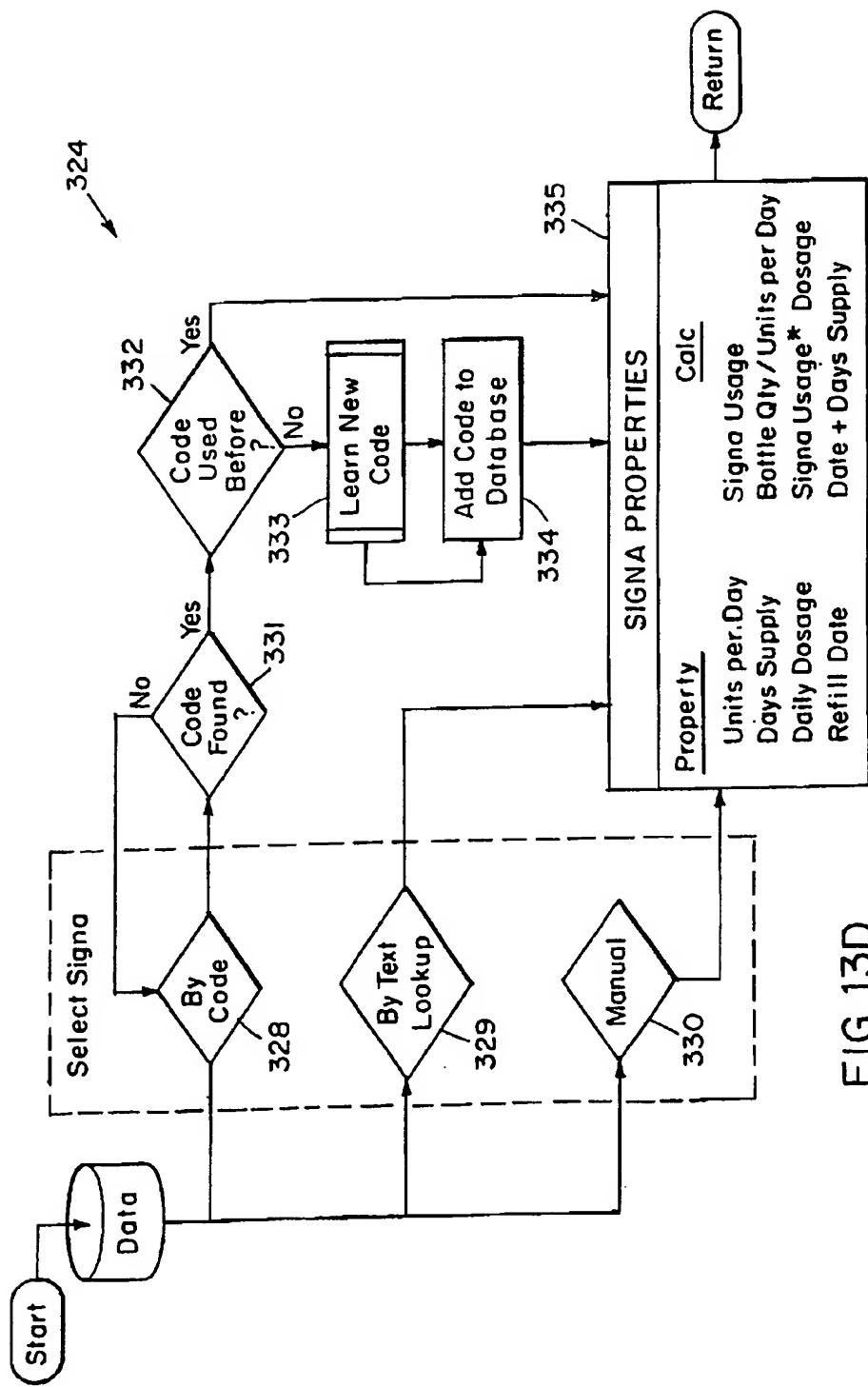


FIG. 13D

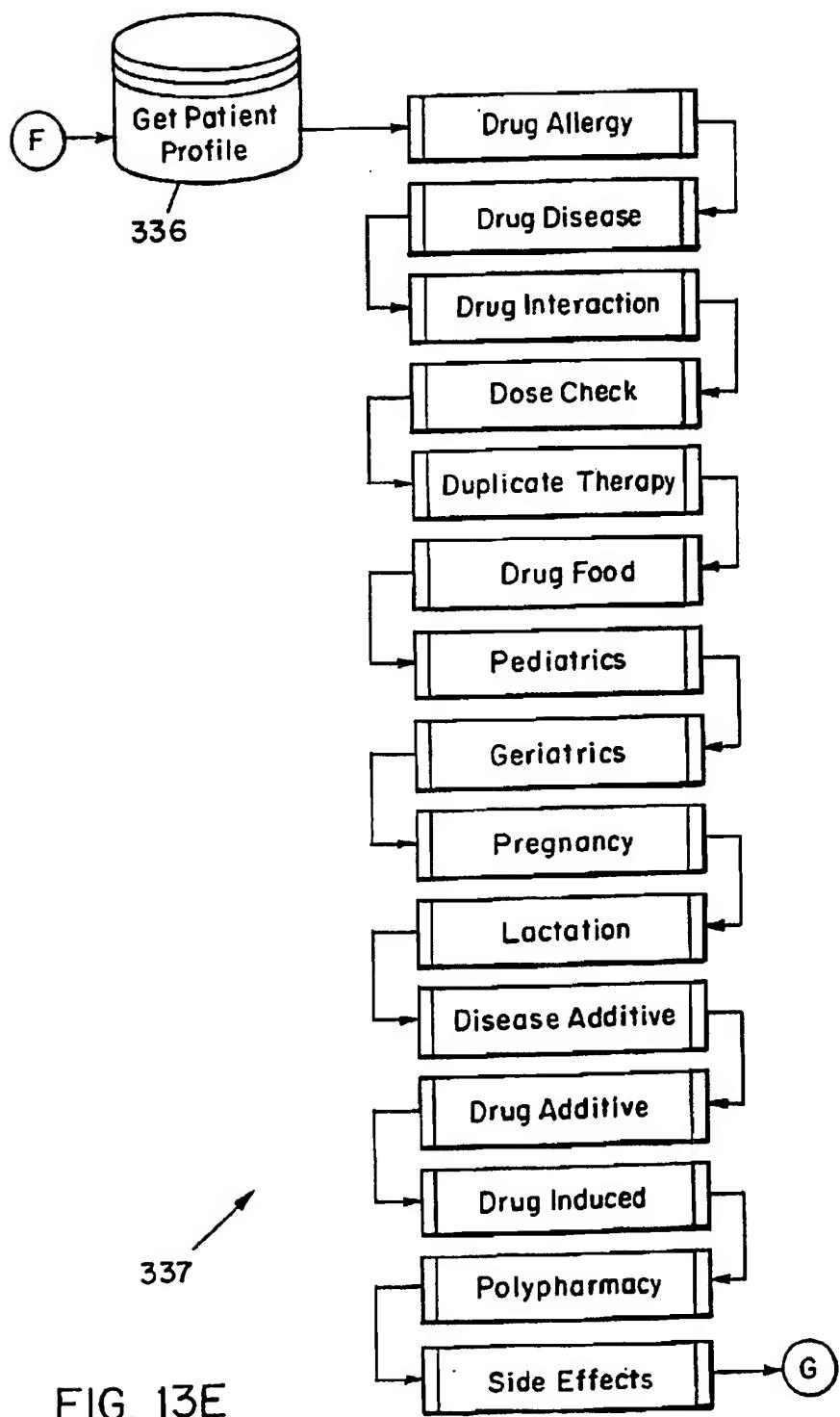


FIG. 13E

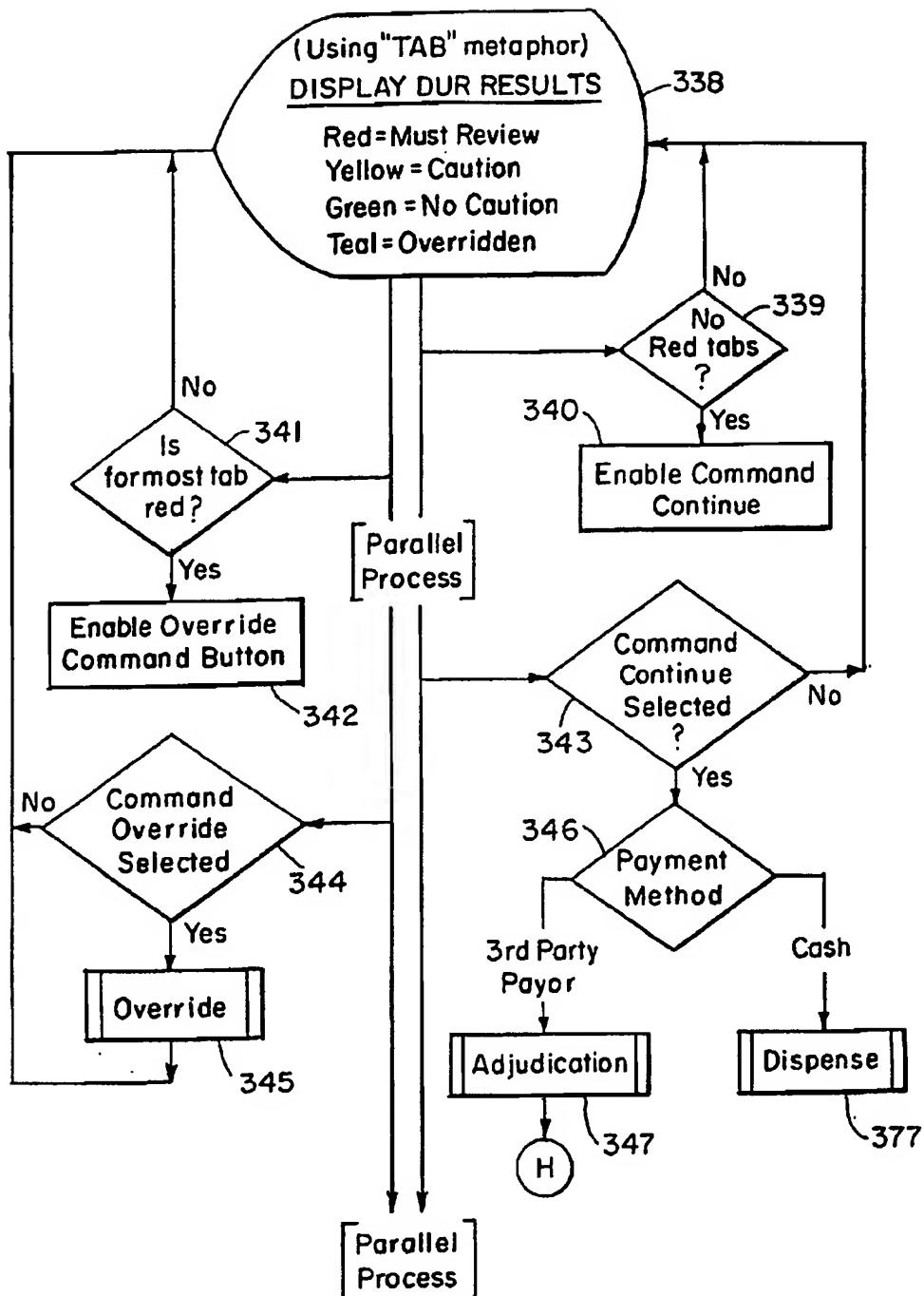


FIG. 13F

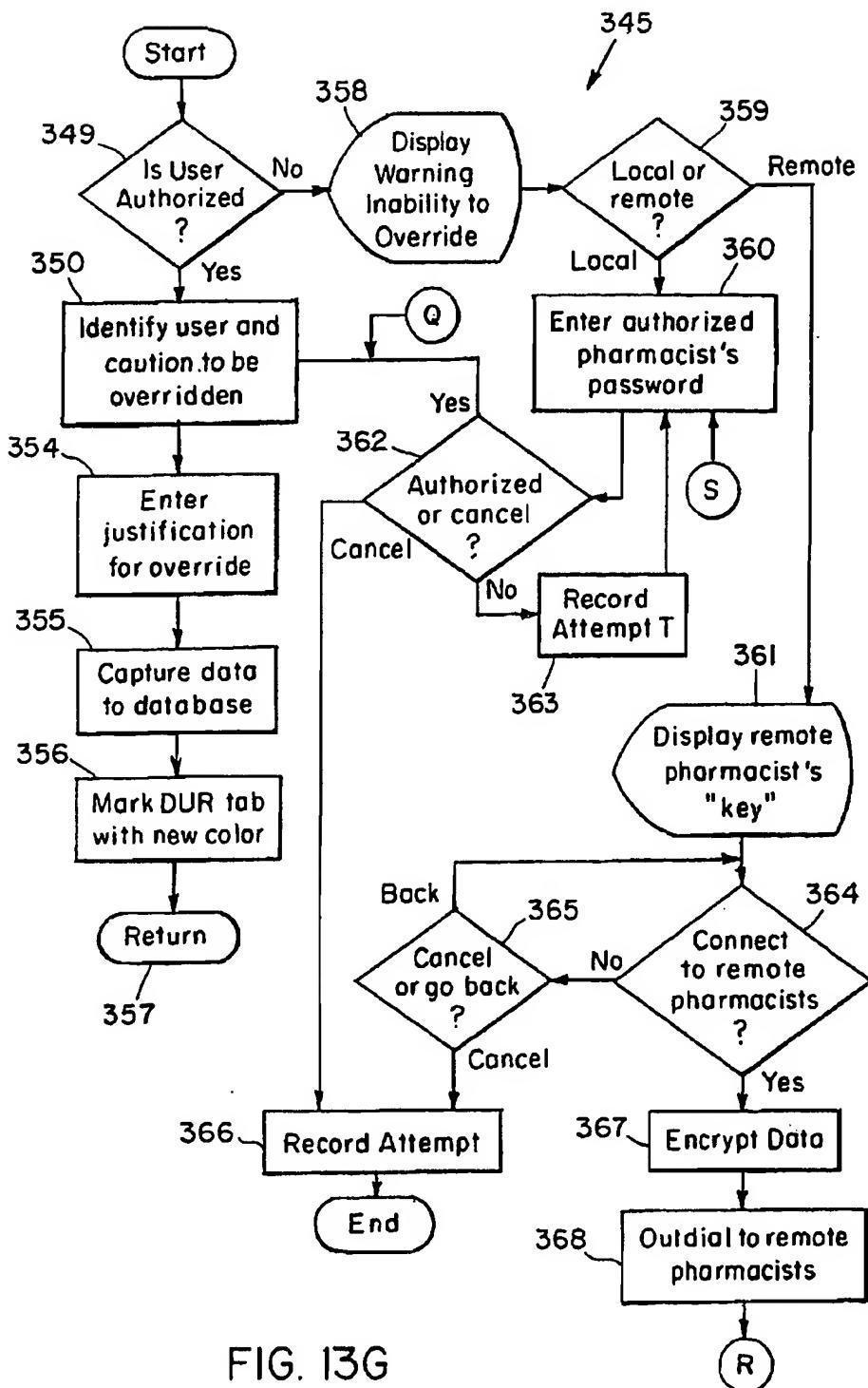


FIG. 13G

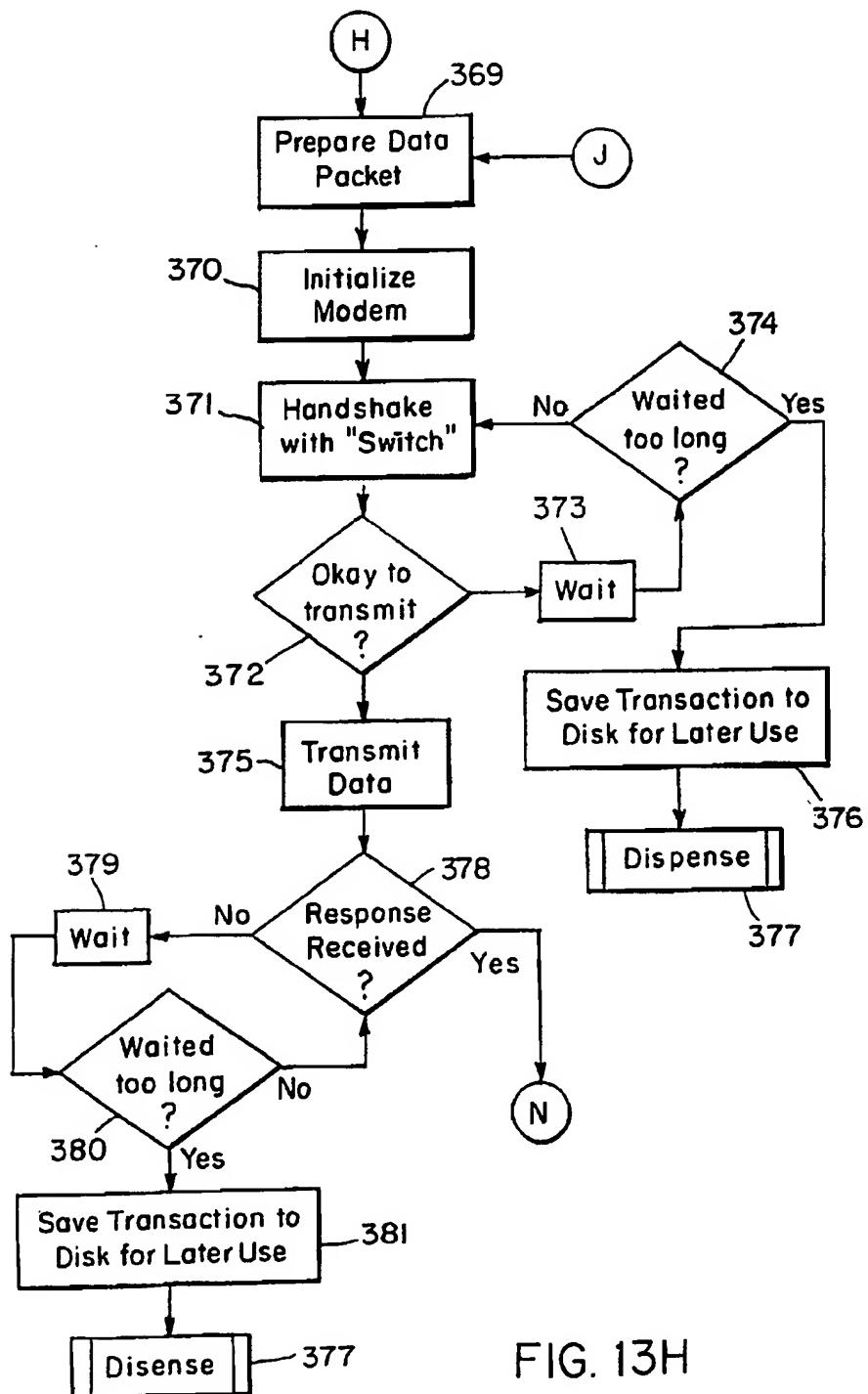


FIG. 13H

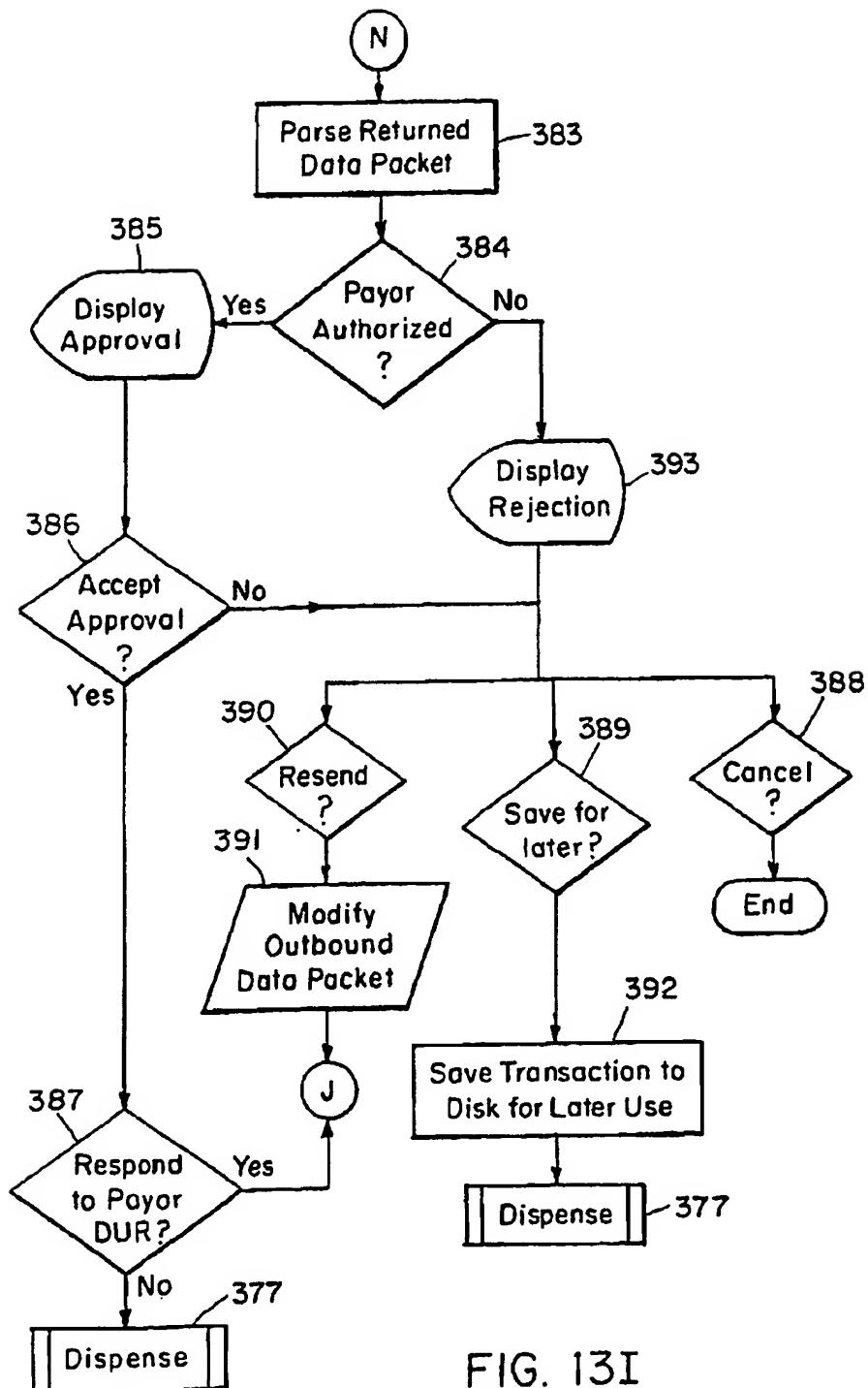


FIG. 13I

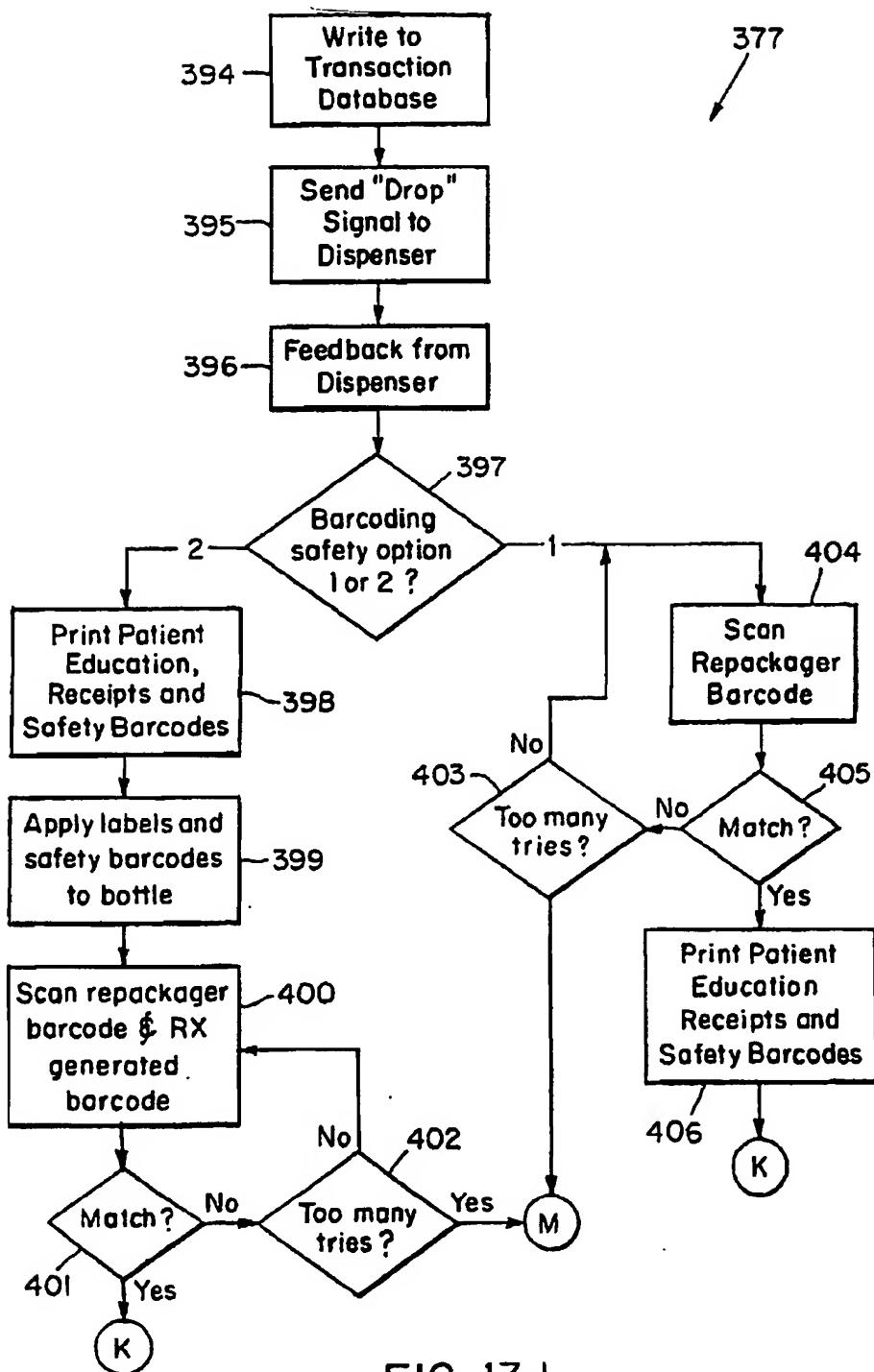


FIG. 13J

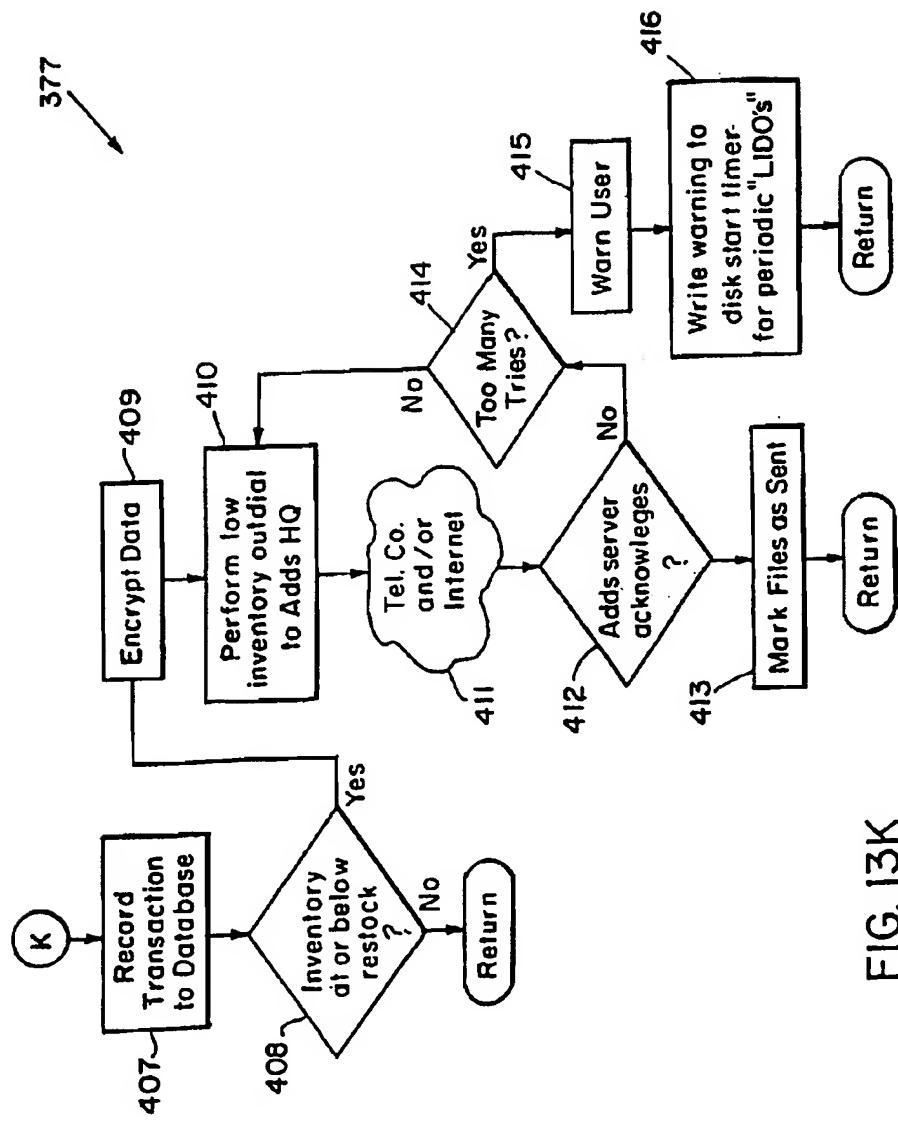


FIG. 13K

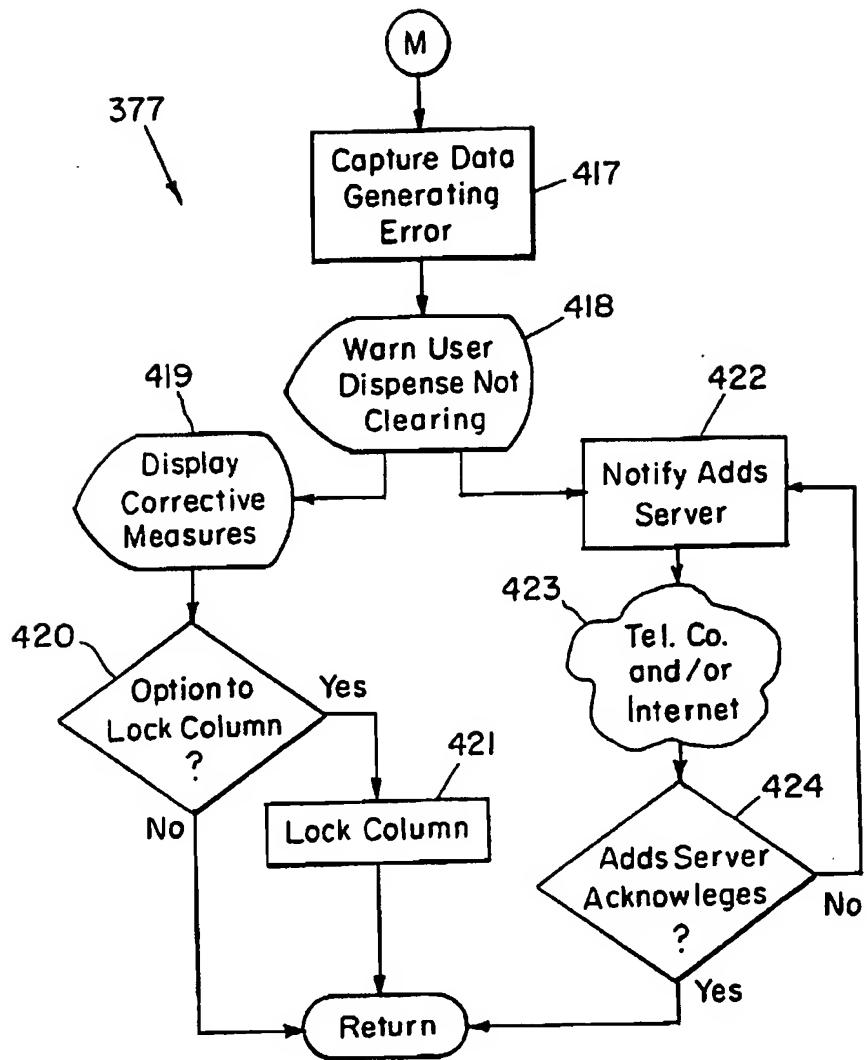


FIG. 13L

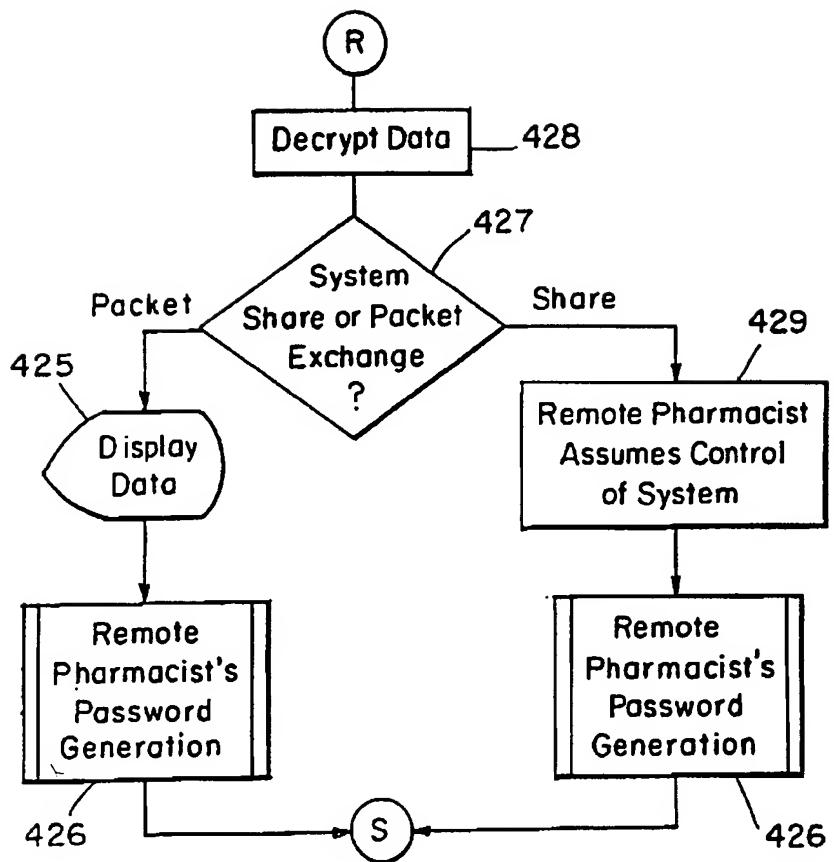


FIG. 13M

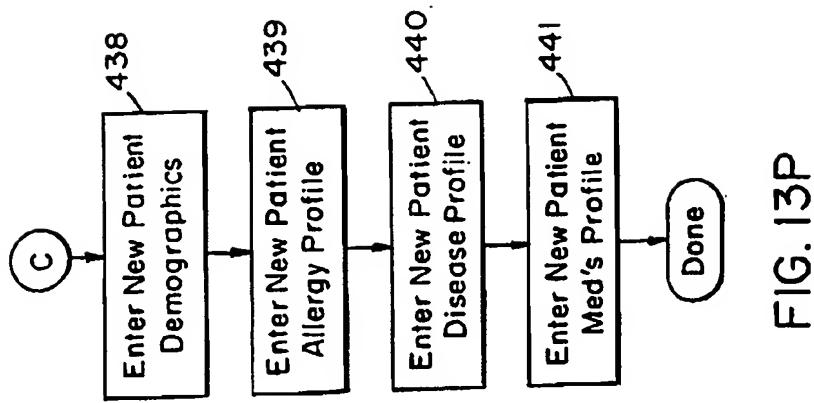


FIG. 13P

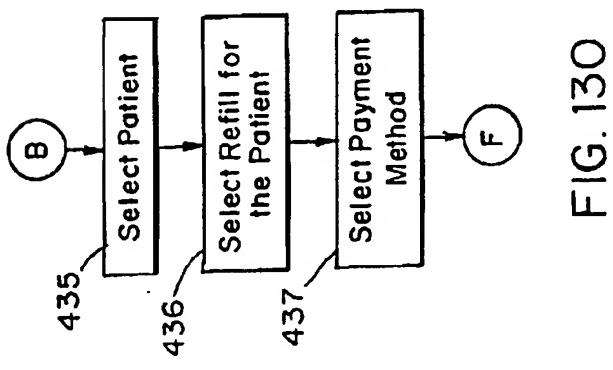


FIG. 13O

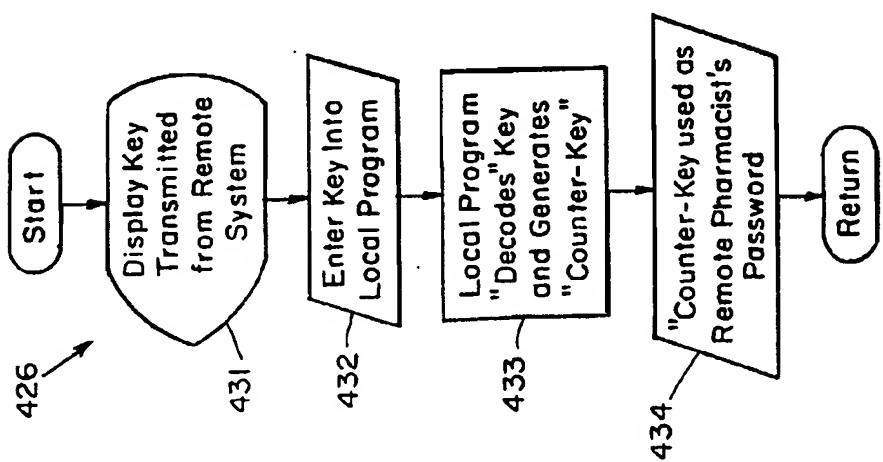


FIG. 13N

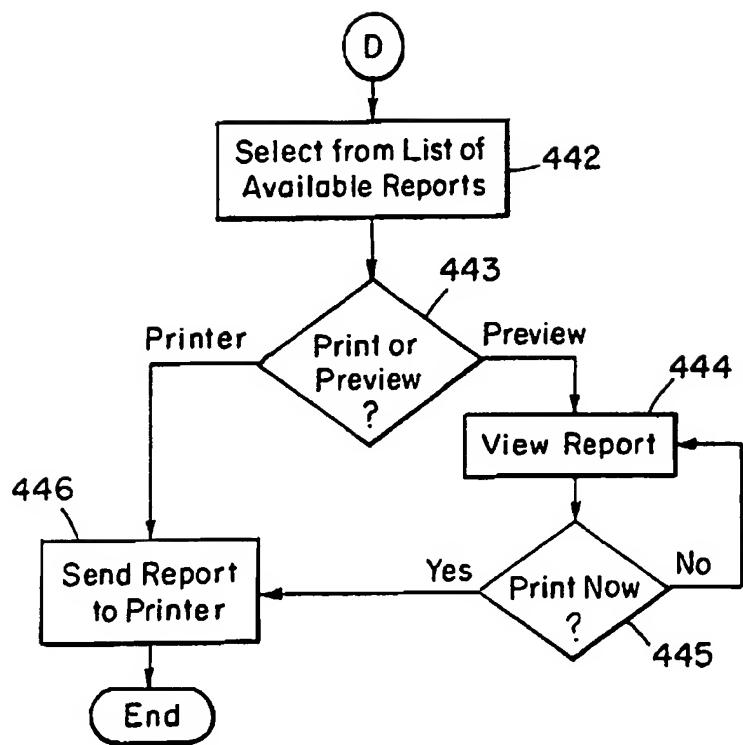


FIG. 13Q

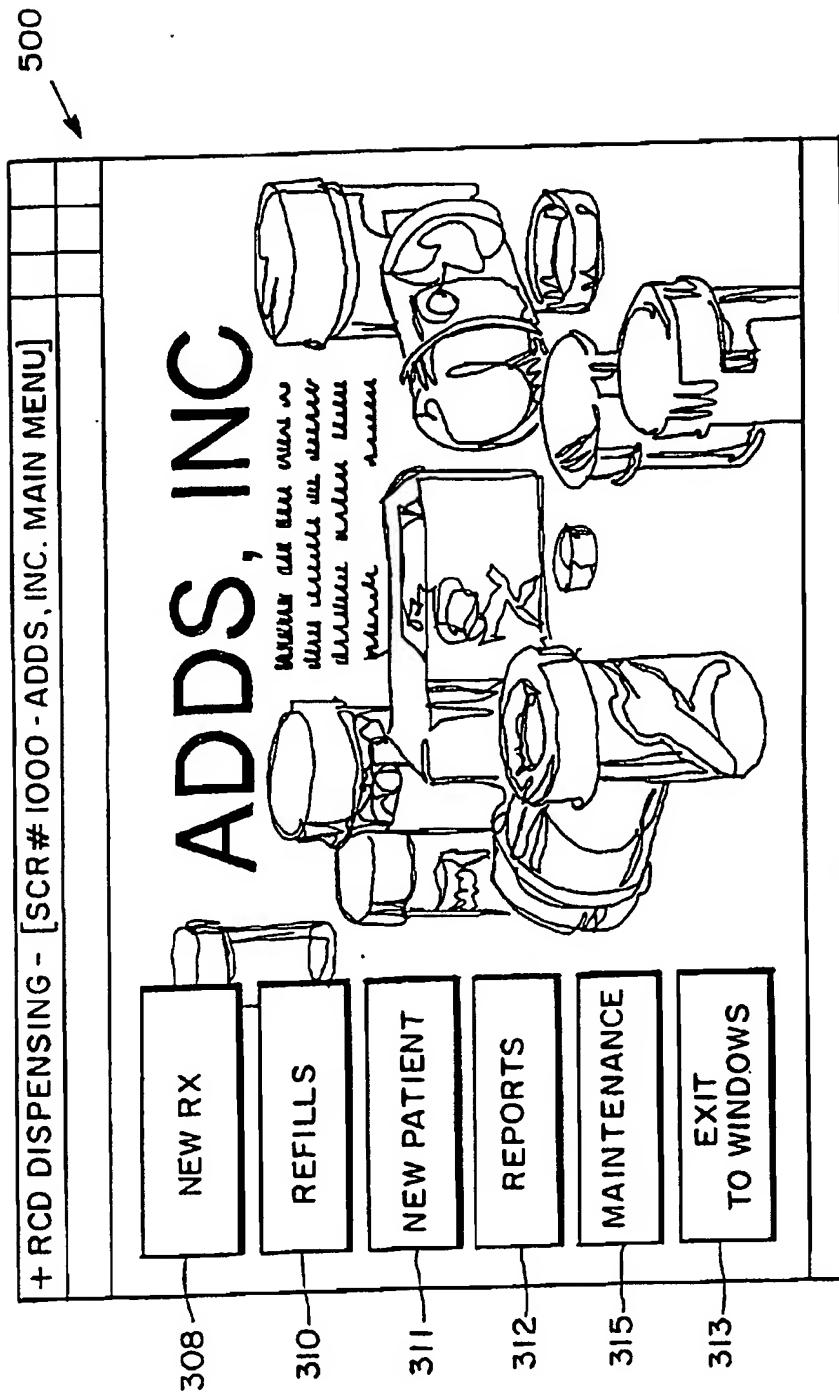


FIG. 14A

+RCD DISPENSING-[SCR #1100-NEW PRESCRIPTION FOR: RUST, MARY ANNE]

Profile	323E	323A	323F	323B	323C	323D
Patient	Payor & Subscriber			Drug	Signa	
Name						
Address				529		
Home Phone		SS No		Patient ID		
Work Phone						
Date of Birth						
Sex						
Weight						
Ethnobiology						
Pregnancy						
Lactation						

FIG. 14B

+RCD DISPENSING [SCR# 1100 - NEW PRESCRIPTION FOR: RUST, MARY ANNE]

Profile	Verify	Payor & Subscriber	Drug	Sign
Patient				
323B				

Prescription Information

● Select Prescriber

ID # 504A  
DEA # 501  
State Lic #  
Phone  
Fax

Prescription Card Service

● Charge  
○ Cash

Group # 56565656  
Card # 17171717  
Last Name: RUSH  
Ref Code: 1  
Per Code: 2  
Testing Data  
Pharm # 770414  
Proc C11 9999999999

Pharmacist Information

● Select Pharmacist

504B

502

FIG. 14C

+ RCD DISPENSING [SCR#1100-NEW PRESCRIPTION FOR: RUST, MARY ANNE]									
Profile		Verify		323C		Drug		Signa	
Patient		Payor & Subscriber		323C		Drug		Signa	
-Drugs Available									
-Generic Name <input type="text"/> 505									
-Brand Name <input type="text"/>									
-NDC Number <input type="text"/>									
-Qty in Bottle <input type="text"/>									
506— <input type="checkbox"/> Branded Generic Substitution									
-ICD-9 Disease Codes—									
-ICD-9 Code <input type="text"/> 507									
GCN <input type="text"/>									
Cabinet <input type="text"/>									
Column <input type="text"/>									
Count <input type="text"/>									

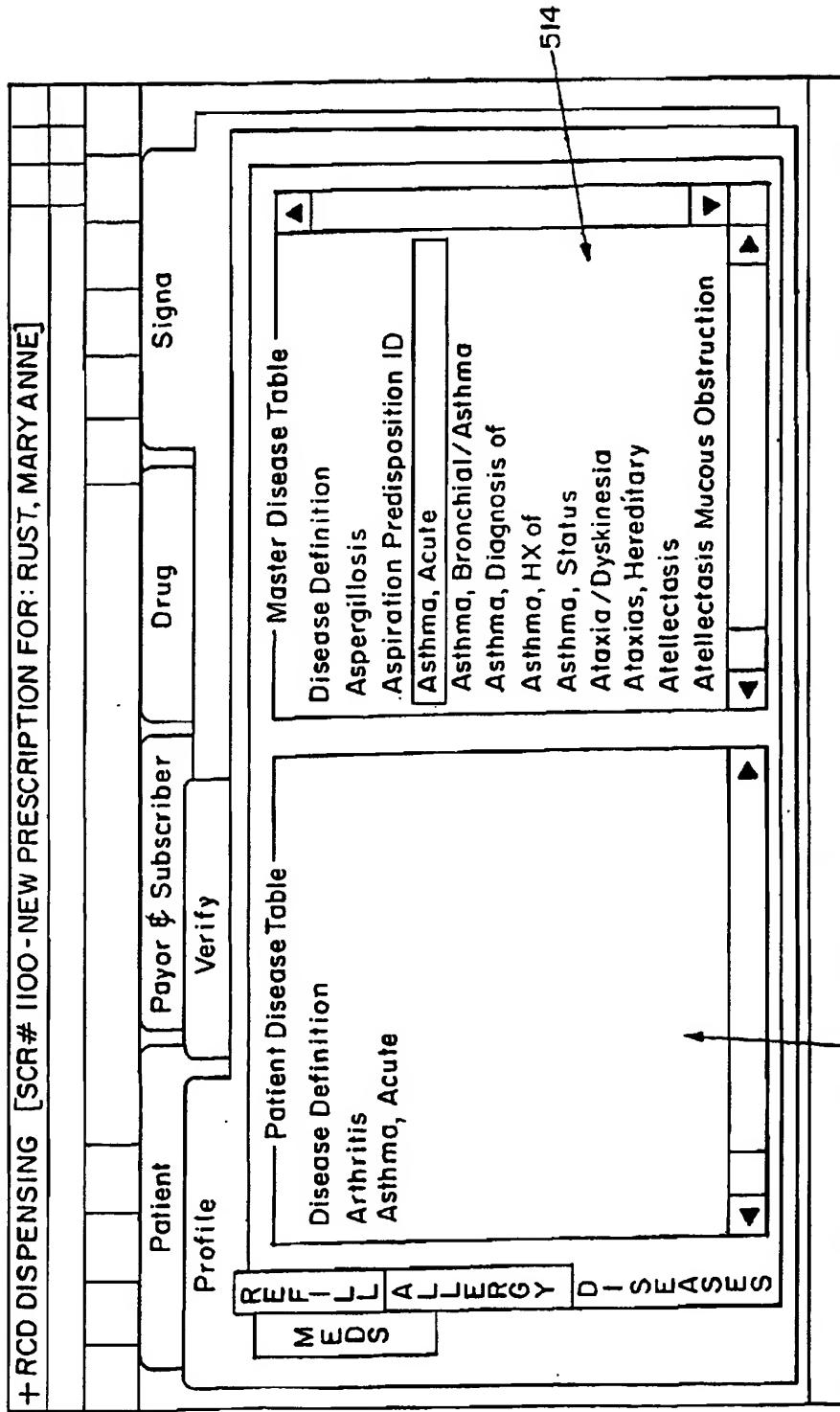
FIG. 14D

+ RCD DISPENSING [SCR# 1100 - NEW PRESCRIPTION FOR: RUST, MARY ANNE]	
Profile	323A
Patient	Verify
328 - By Code	323B
329 - By Test	323C
330 - Manual	Drug
Units per Day	3
Refills	99
Date Written	3/2/96
Take 1 Tablet Three Times Daily with Meals	
Daily Dose	030 mg
Days Supply	40
Signature	
Code Defaults	
Substitution not allowed by Subscriber	▼ 1
Skilled Care Facility	▼ 07
Telephone Script	▼ 2
Compound	▼ 2

FIG. 14E

+ RCD DISPENSING [SCR# 1100 - NEW PRESCRIPTION FOR: RUST, MARY ANNE]																																							
508	Profile	Patient	323E	Payor & Subscriber	Drug	Signs																																	
512																																							
513																																							
<table border="1"> <thead> <tr> <th colspan="10">Patient Allergy Table</th> </tr> </thead> <tbody> <tr> <td colspan="10">None Found</td> </tr> <tr> <td colspan="10">           Allergy Definition            Acetaminophen            Warfarin            Tetracyclines         </td> </tr> </tbody> </table>										Patient Allergy Table										None Found										Allergy Definition Acetaminophen Warfarin Tetracyclines									
Patient Allergy Table																																							
None Found																																							
Allergy Definition Acetaminophen Warfarin Tetracyclines																																							
<table border="1"> <thead> <tr> <th colspan="10">Master Allergy Table</th> </tr> </thead> <tbody> <tr> <td colspan="10">           Allergy Definition            Rauwolfia alkaloides            Salicylates            Skeletal muscle relaxants (CARBA)            Tetanus Toxoid  <b>Tetracyclines</b>            Thiazides Sulphonamide Sulfonide            Trimethuprim            Vaccines            Warfarin            Xanthines            Zidovudine         </td> </tr> </tbody> </table>										Master Allergy Table										Allergy Definition Rauwolfia alkaloides Salicylates Skeletal muscle relaxants (CARBA) Tetanus Toxoid <b>Tetracyclines</b> Thiazides Sulphonamide Sulfonide Trimethuprim Vaccines Warfarin Xanthines Zidovudine																			
Master Allergy Table																																							
Allergy Definition Rauwolfia alkaloides Salicylates Skeletal muscle relaxants (CARBA) Tetanus Toxoid <b>Tetracyclines</b> Thiazides Sulphonamide Sulfonide Trimethuprim Vaccines Warfarin Xanthines Zidovudine																																							

FIG. 14F



515

FIG. 14G

+ RCD DISPENSING [SCR# 1100 - NEW PRESCRIPTION FOR: RUST, MARY ANNE]									
Patient		516		Payor & Subscriber		Drug		Signa	
Profile		Verify							
R E F - L U A R E A U L E R G Y		M E D S L U A S E A S E S		Active Meds		Available Optional Meds		Inactive Meds	
Dispensed 8/24/96 8/28/96 8/29/96		Drug Brand Name Norflex Prilosec Ketoprofen		Drug Brand Name Kerodex 5I Kerodex 5I Kerodex 7I Kerodex 7I		Drug Brand Name Drudis		Drug Brand Name Ketobias HX Reagent Ketoprofen Ketoprofen	
3/29/96									
D - S E A S E S									

58

FIG. 14H

51

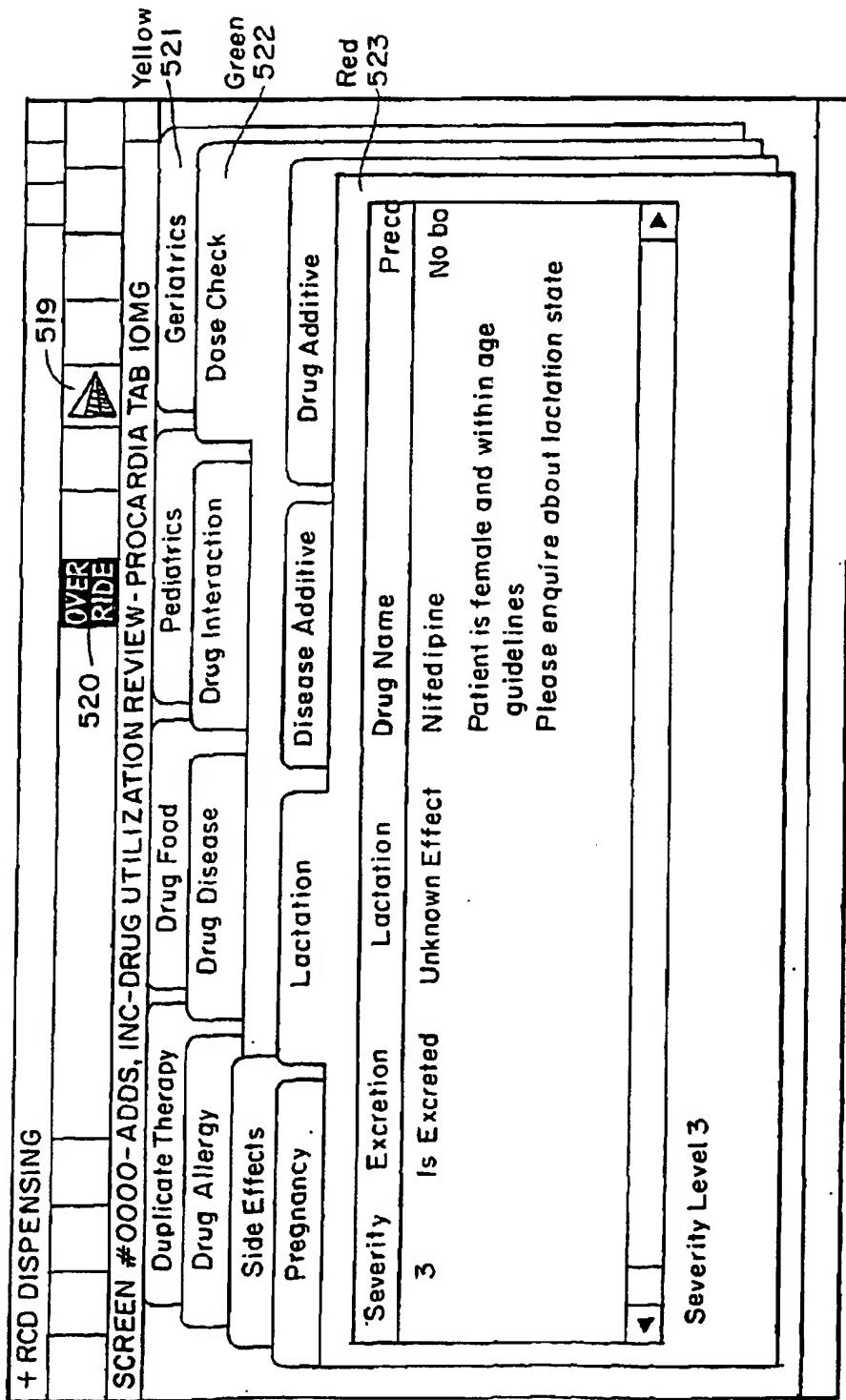


FIG. 141

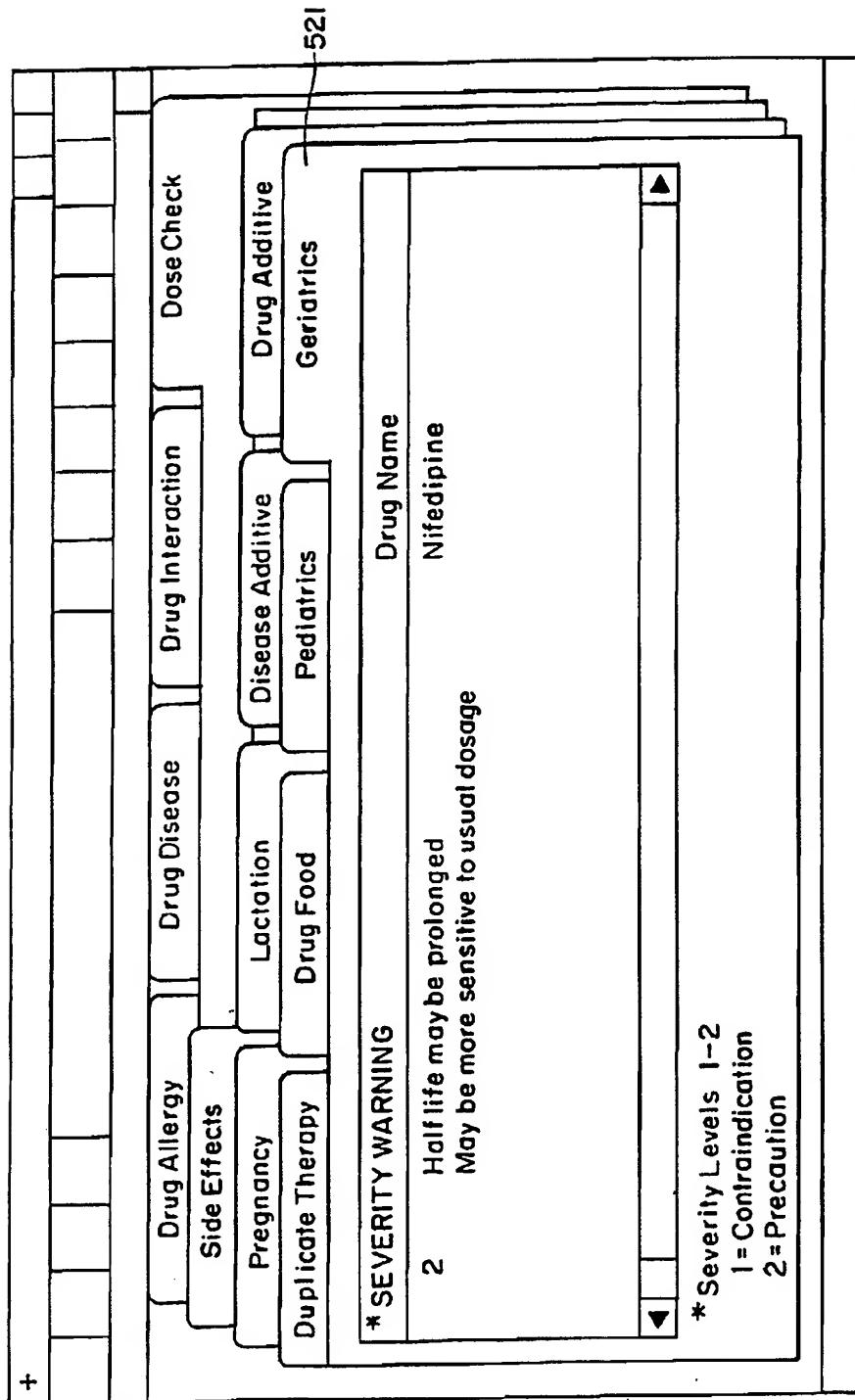


FIG. 14.J

+ RCD DISPENSING [SCR# 1100-NEW PRESCRIPTION FOR: RUST, MARY ANNE]									
519	519	519	519	519	519	519	519	519	519
Patient Profile		323F		Payor & Subscriber		Drug		Signa	
Patient Information									
Rust, Mary Anne 156 Main St Suite B Portland, OR 012345 Home (888) 888-8888 Work (888) 888-8888		SSNo: 812439876 ID: RUSTMA001 DOB: 9/15/65		Drug Brand: Procardia tab 10mg Generic: Nifedipine tab 10mg In Bottle, 120 NDC00069-2600-1 In Stock, 33		Signa		Trouble Shooting Column 1 Cabinet 1	
Payor									
Prescription Card Service									
Prescriber									
Dr. Jones, Ralph		ICD-9		Dispense as written Code 1		Take 1 Tablet 3 Times Daily w/Meals		Adjudication Information	
Diagnostics on Brain		ICD-9		Location Code 07		Origin Code 2		Compound Code 2	

FIG. 14K

Date & Time	3/29/96 3:17:00 PM	SAVE	526
Operator ID	DEMO	CANCEL	
Overriding	LACTATION		
Conflict	DRUG PREGNANCY ALERT	▼	
Intervention	PREScriber CONSULTED	▼	
Outcome	FILLED AS IS	▼	
Override Comments	PREScriber CLEARED DISPENSING	▼	525
Trouble Shooting View			
Rx68 Capture			

FIG. 14L

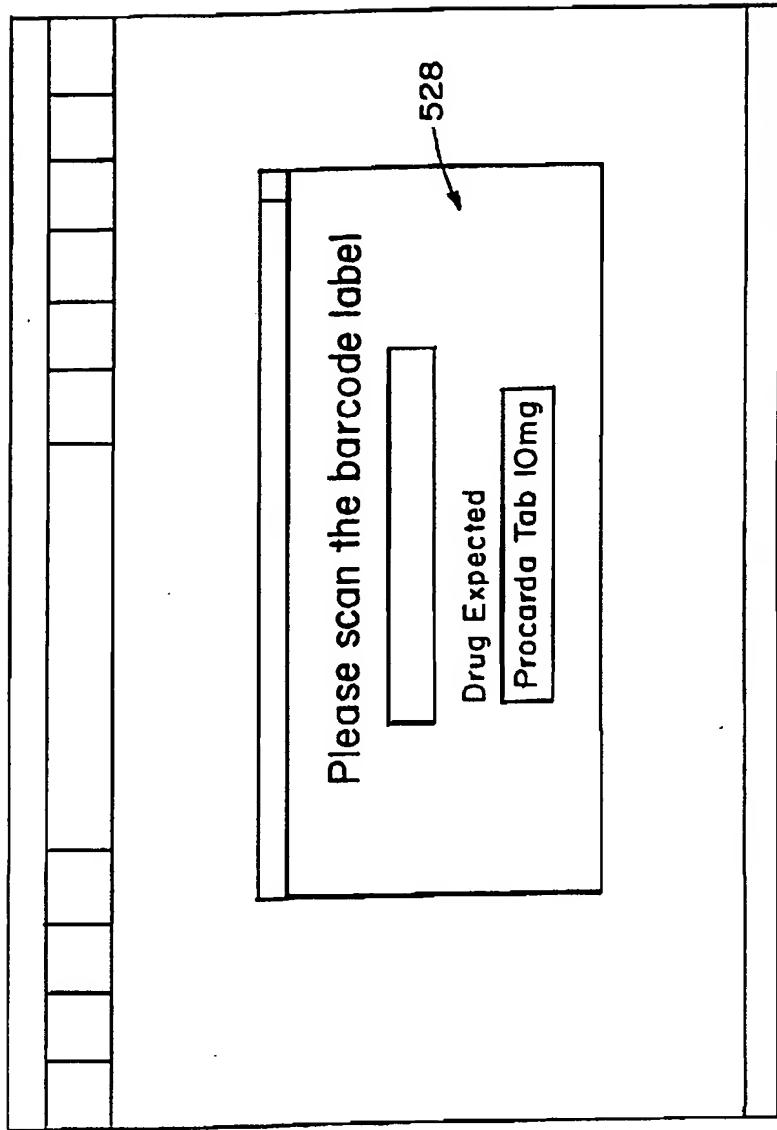


FIG. 14M

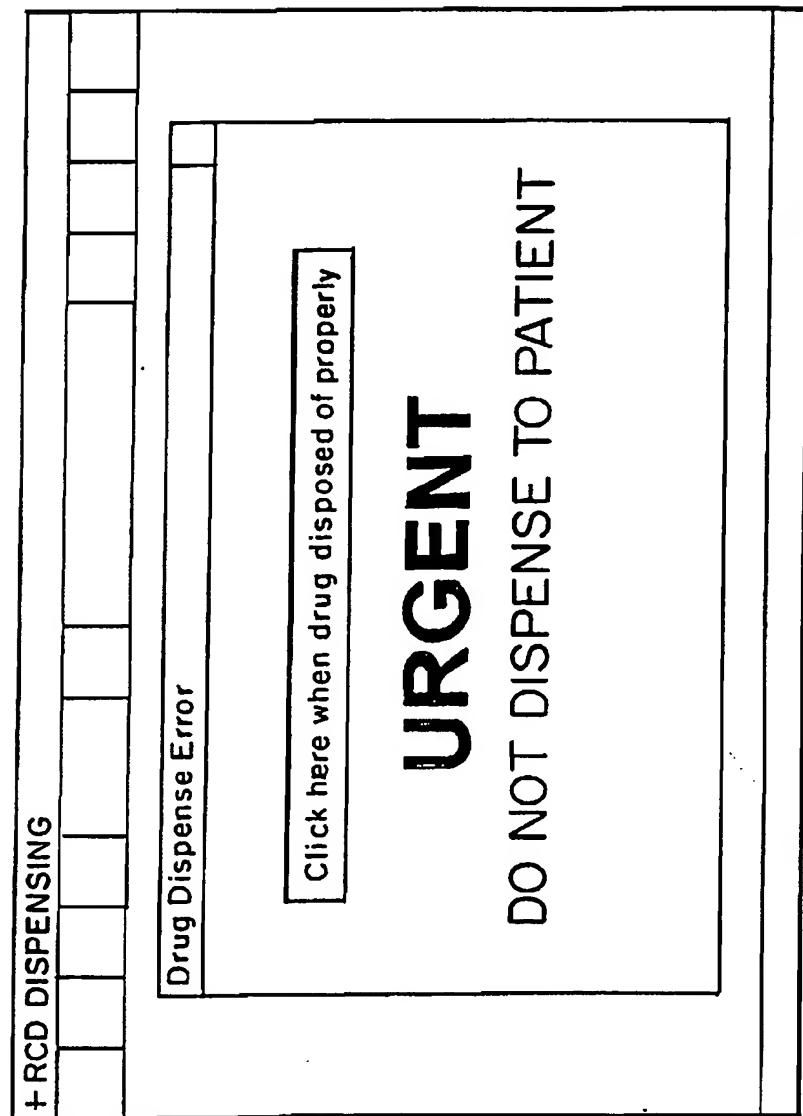


FIG. 14N

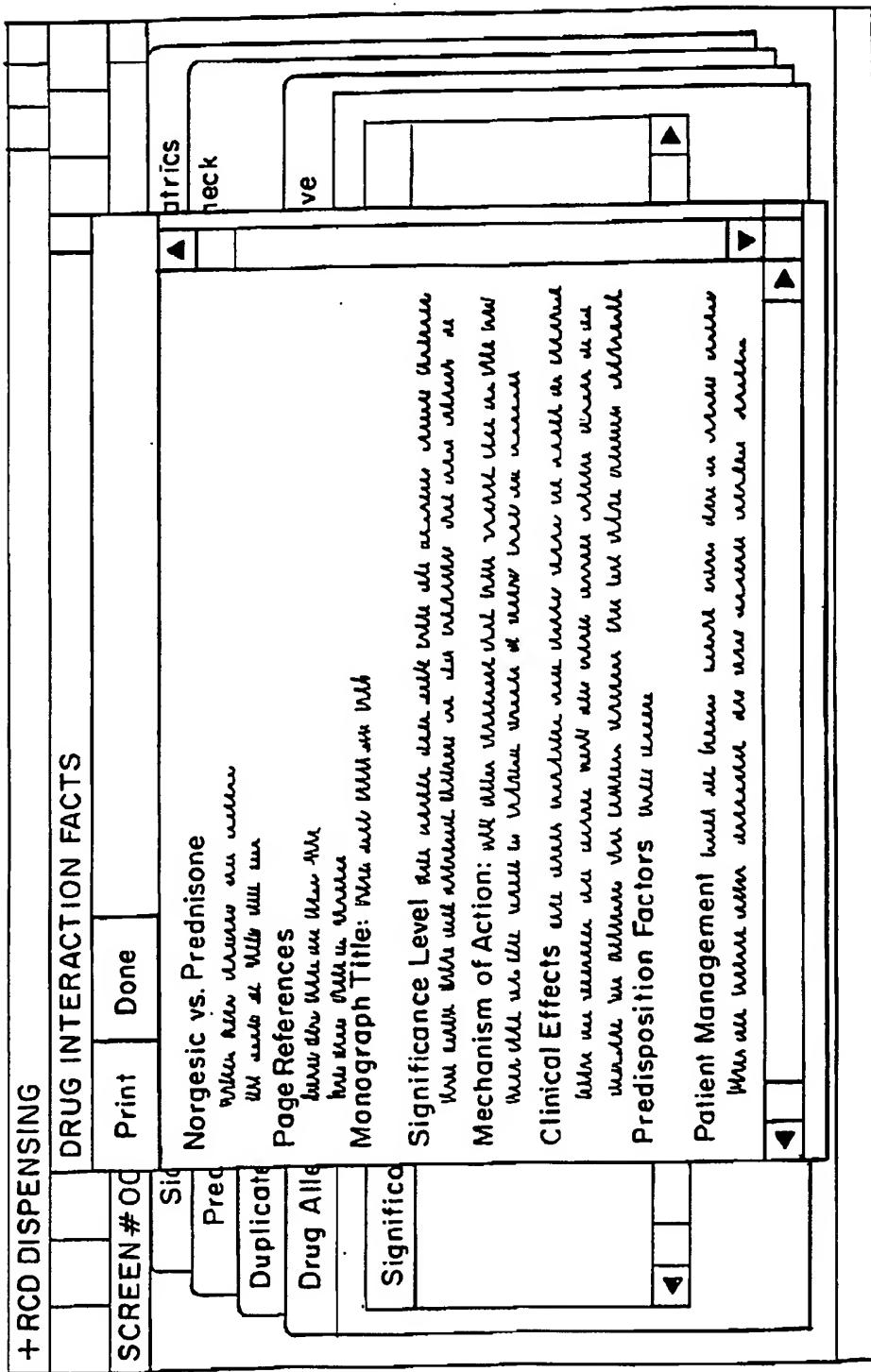


FIG. 140

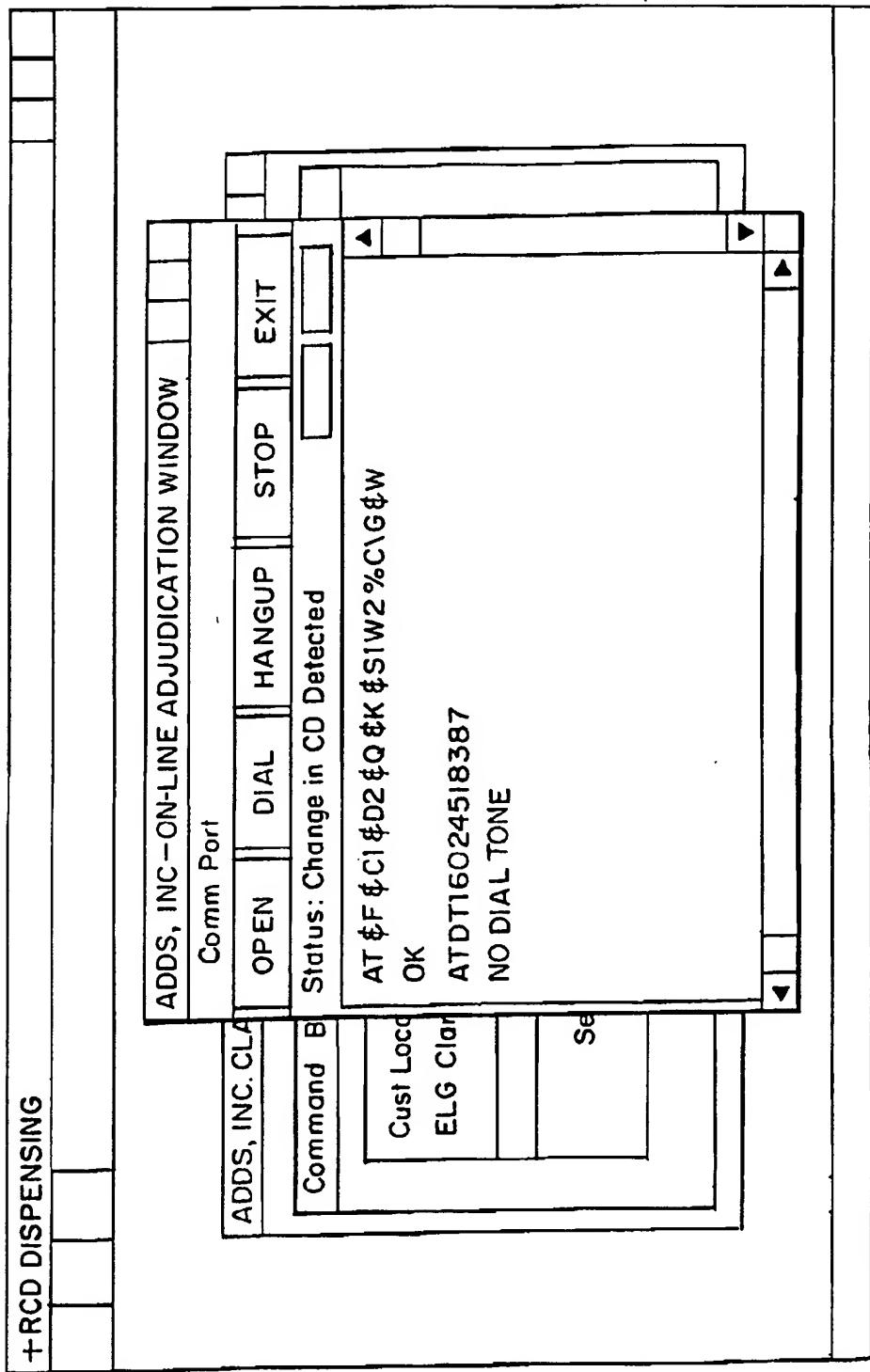


FIG. 14P

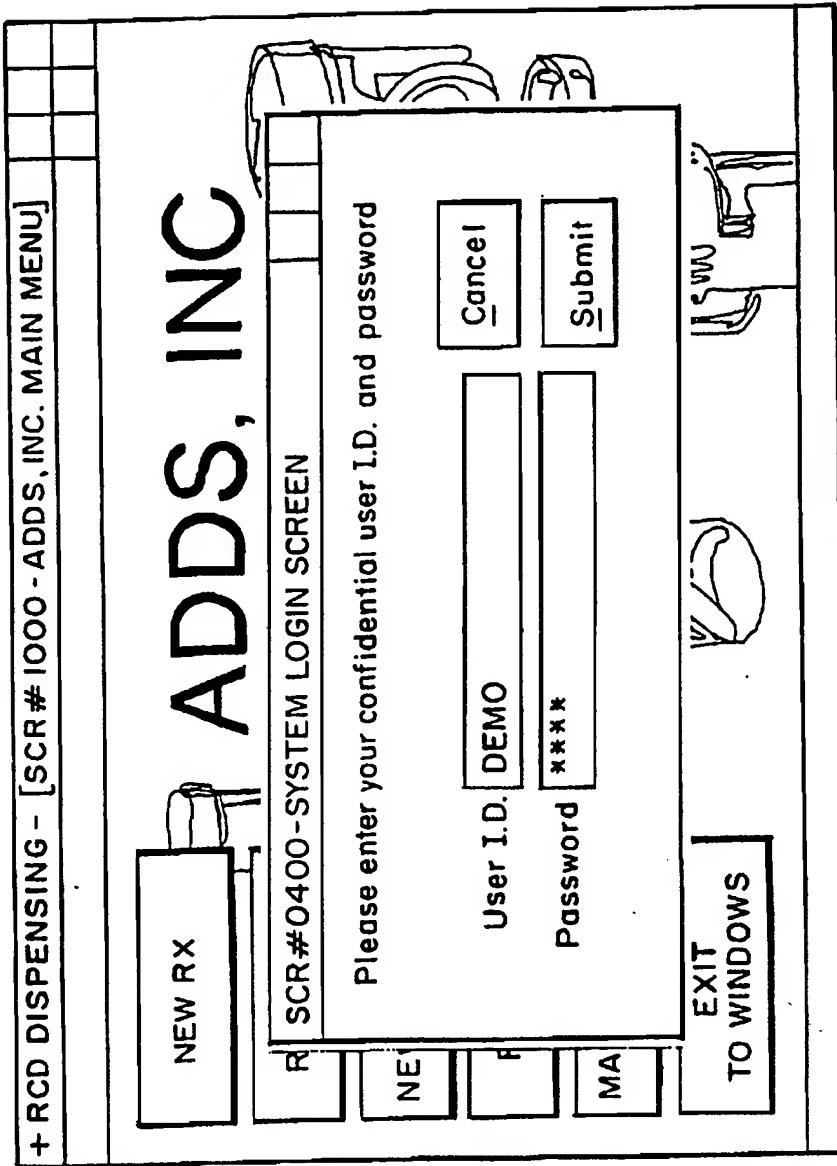


FIG. 14Q

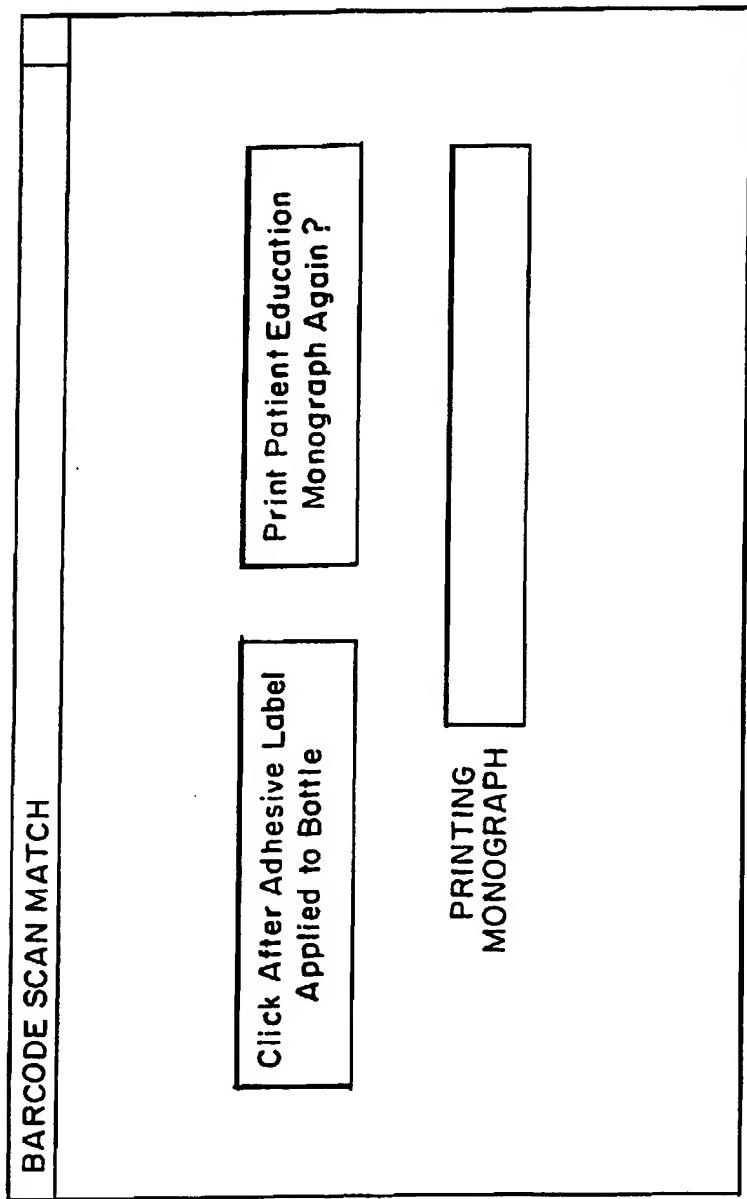


FIG. 14R

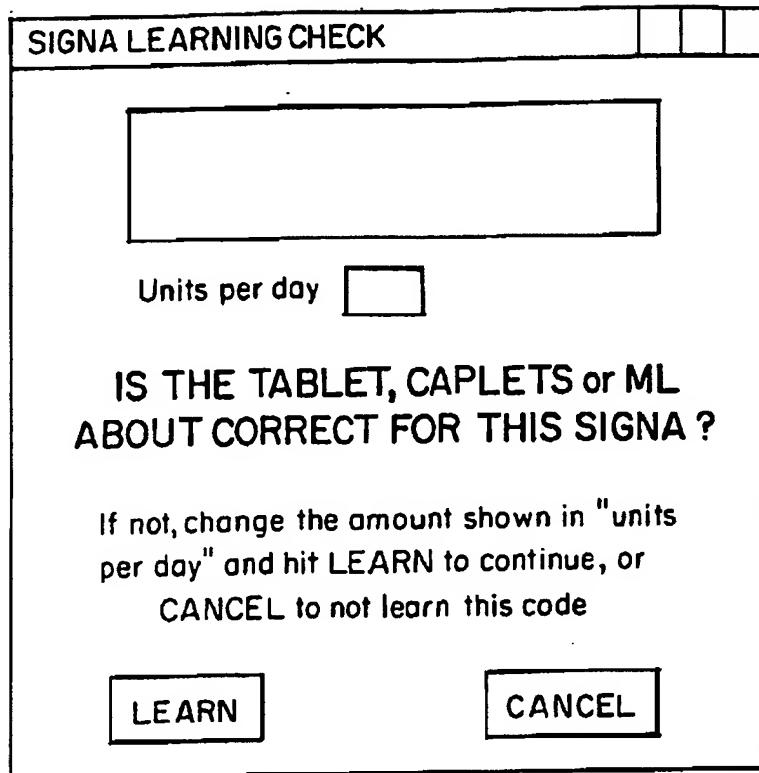


FIG.14S

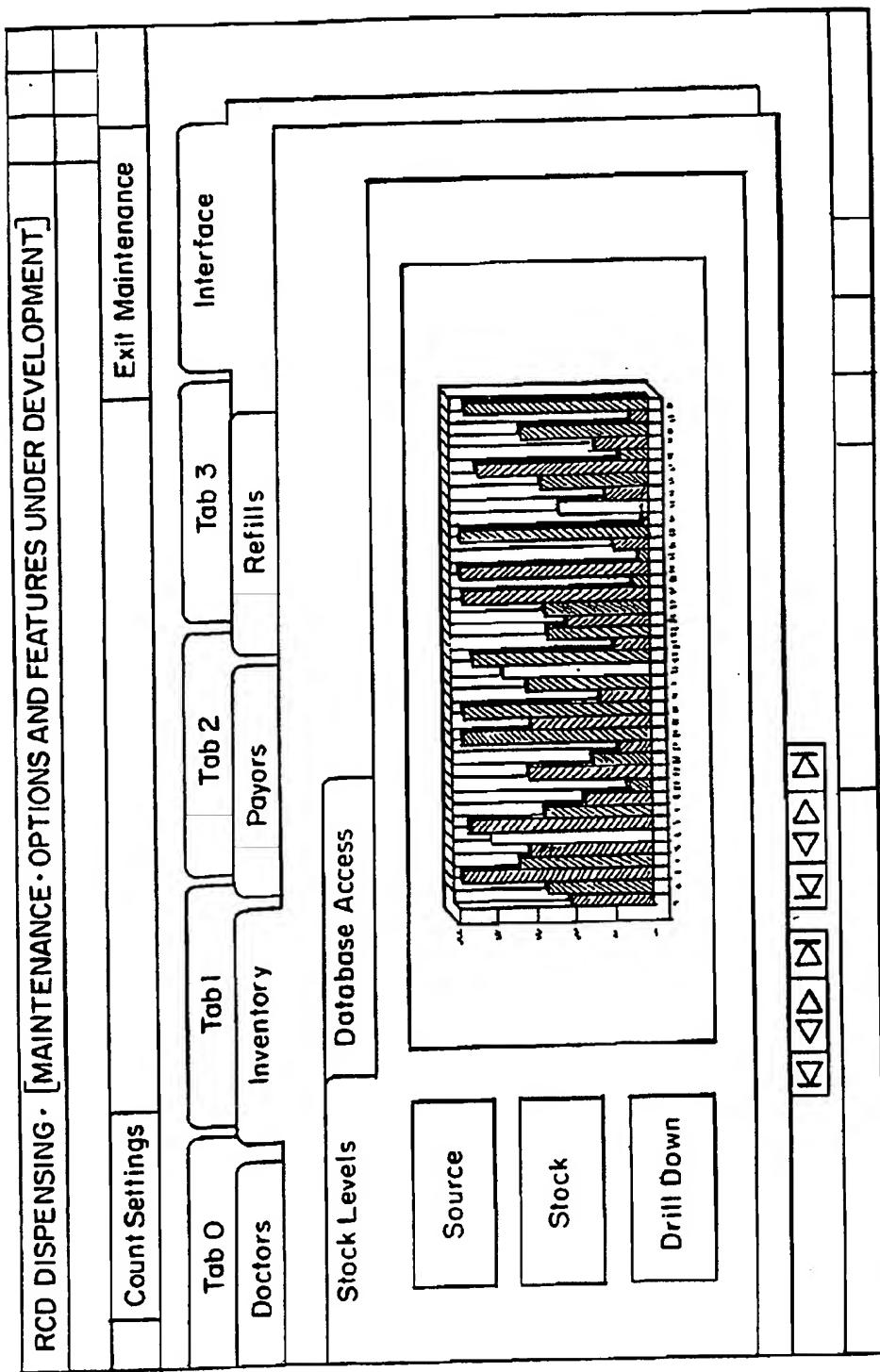


FIG. 14T

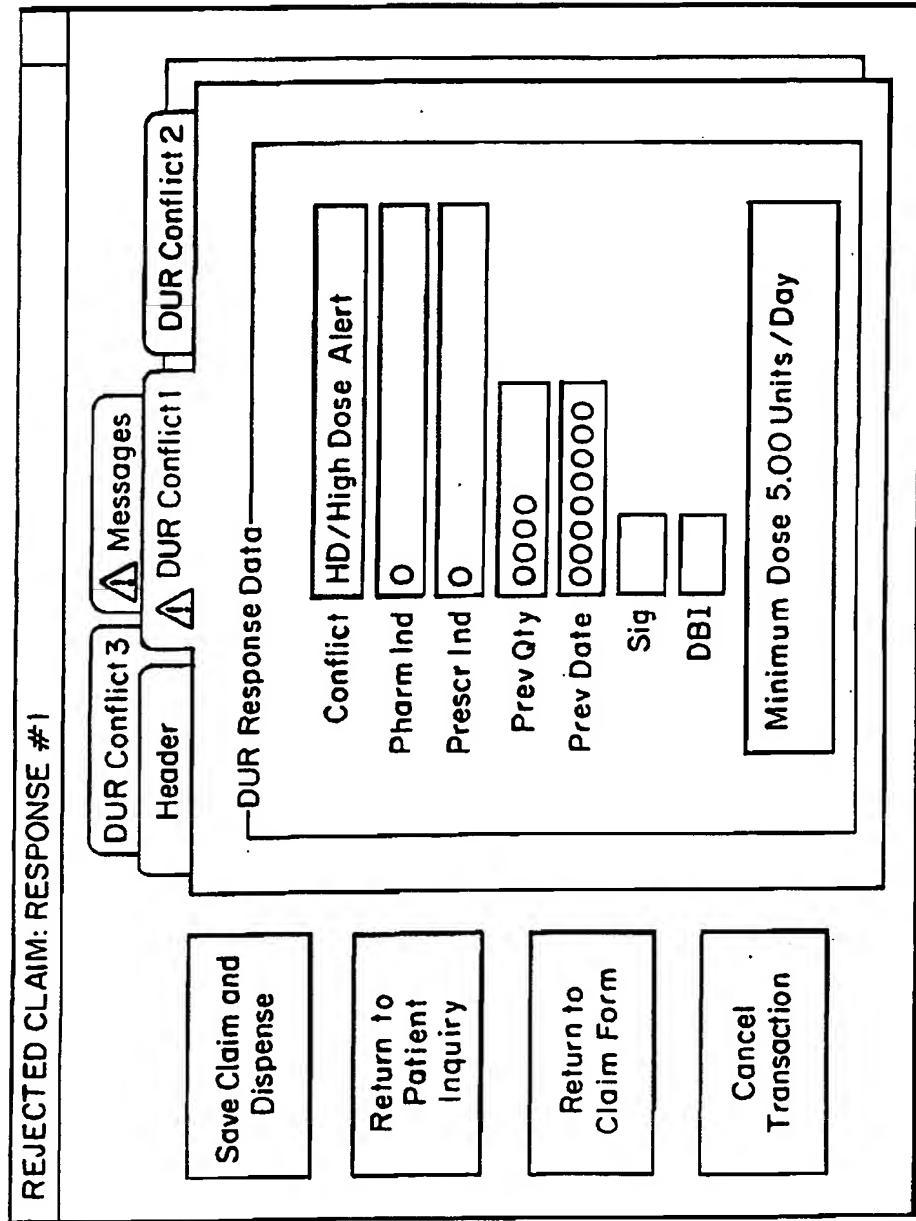
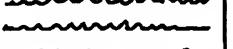
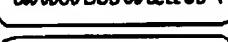
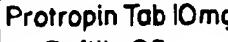


FIG. 14U

DUR RESPONSE INTERVENTION		
DUR 1	DUR 2	DUR 3
DUR Response Data 1		
Conflict	HD/High Dose Alert	Sig <input type="checkbox"/>
Pharm Ind O		DBI <input type="checkbox"/>
Prescr Ind O		
Prev Qty <input type="checkbox"/> 00000	Prev Date <input type="checkbox"/> 00000000	
Minimum Dose 5.00 Units/Day		
Intervention	<input type="checkbox"/>	<input type="checkbox"/>
Outcome	<input type="checkbox"/>	<input type="checkbox"/>
Comments	<input type="checkbox"/>	
RX Number	<input type="checkbox"/>	
9157	<input type="checkbox"/>	
<input type="checkbox"/> DONE	<input type="checkbox"/> SKIP	

FIG. 14 V 525

<b>PHARMACY</b> Roc 9157 Fill: 05-02 <b>TAKE 1 TABLET AT BEDTIME</b> Protropin Tab 10mg Somatrem Tab 10mg/ Count: 4 Lot#: 123456 Expiry: 12/99 Claim Auth: Price: 88 Refills left To Refill call 800-4 Refill PC2000 DEMO 0/34/JQS Dr. Jones, Ralph		Keep all doctor's visits and lab appointments 
		John Doe 
		
Roc 9157 John Doe Take 1 Tablet at Bedtime	Roc 9157 John Doe Take 1 Tablet at Bedtime	
Protropin Tab 10mg Refills: 88		Protropin Tab 10mg Refills: 88

---

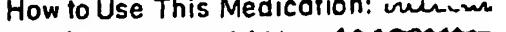
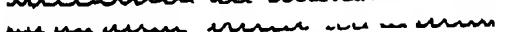
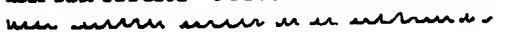
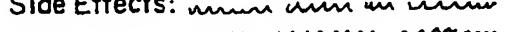
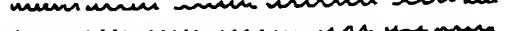
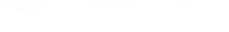
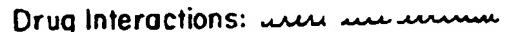
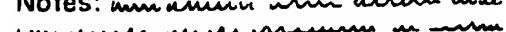
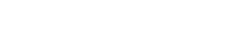
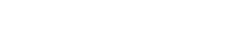
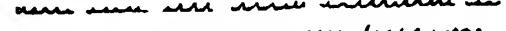
Patient Education Monograph	Rx 9157	Date: 05-02-1996
Somatrem Injection	JOHN DOE	
Uses: 	TAKE 1 TABLET AT BEDTIME	
How to Use This Medication: 	Dr Jones, Ralph	
	Protropin Tab 10mg	
	Count: 4 Lot#: 123456	
	Claim Auth:	
Side Effects: 	Expiry: 12/99 Price:	
		
Precautions: 		
Drug Interactions: 		
Notes: 		
		
Missed Dose: 		
		
Storage 		

FIG. 15

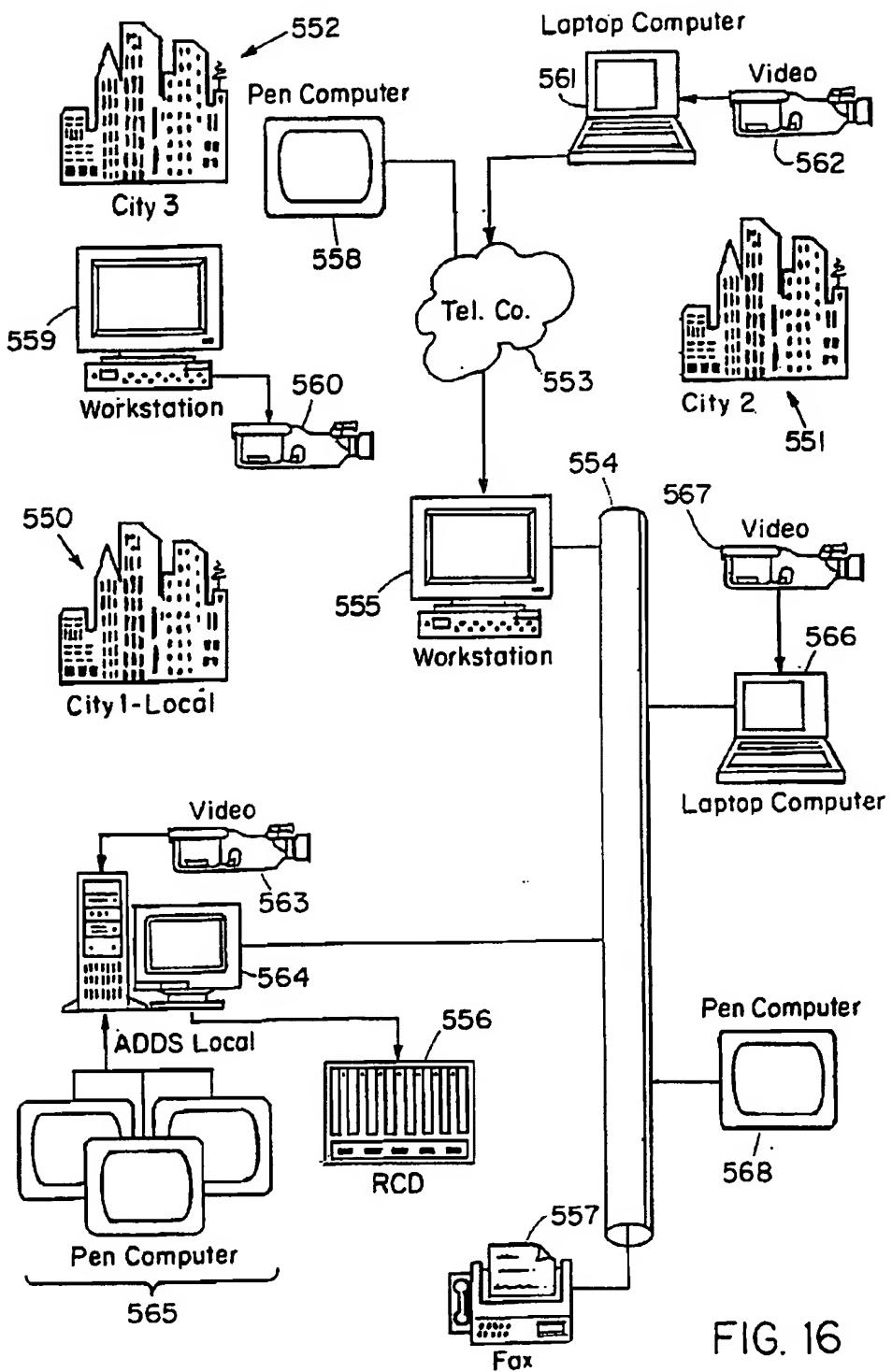


FIG. 16

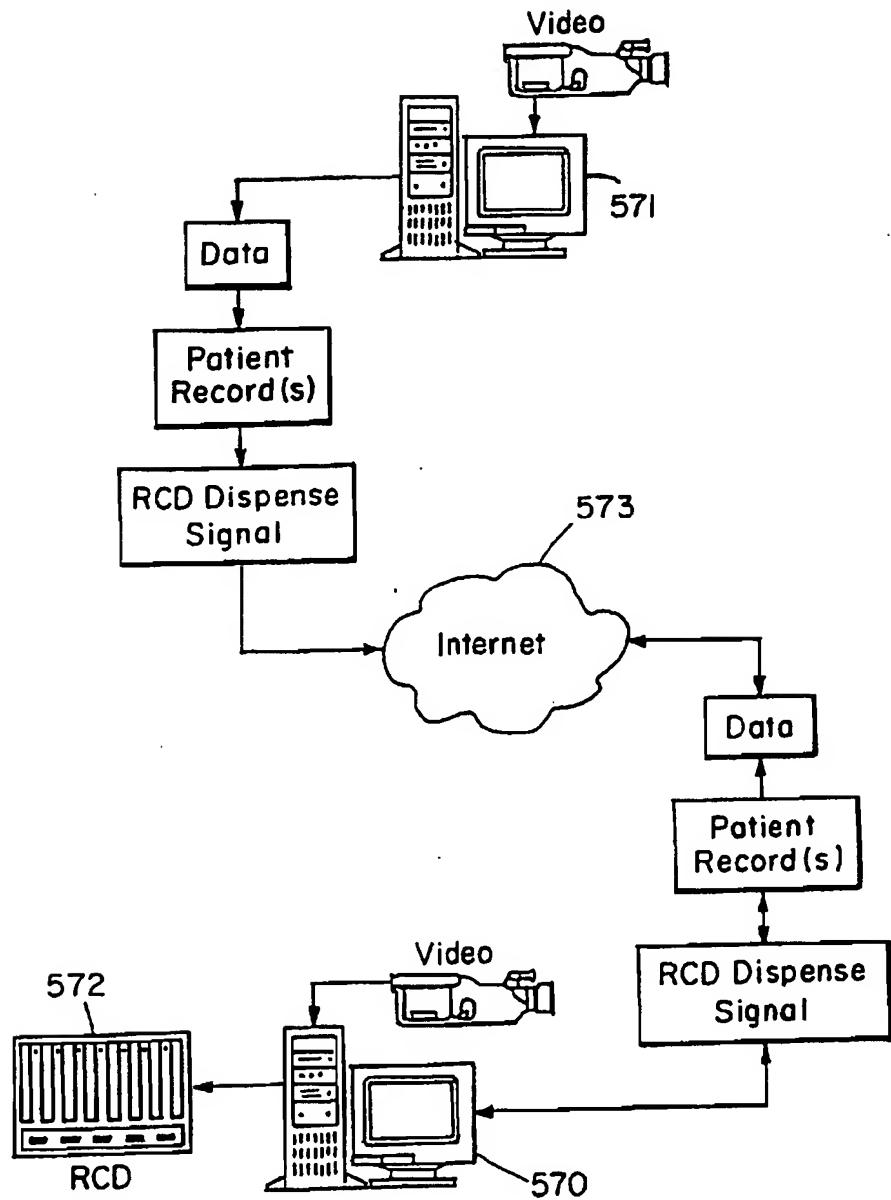


FIG. 17

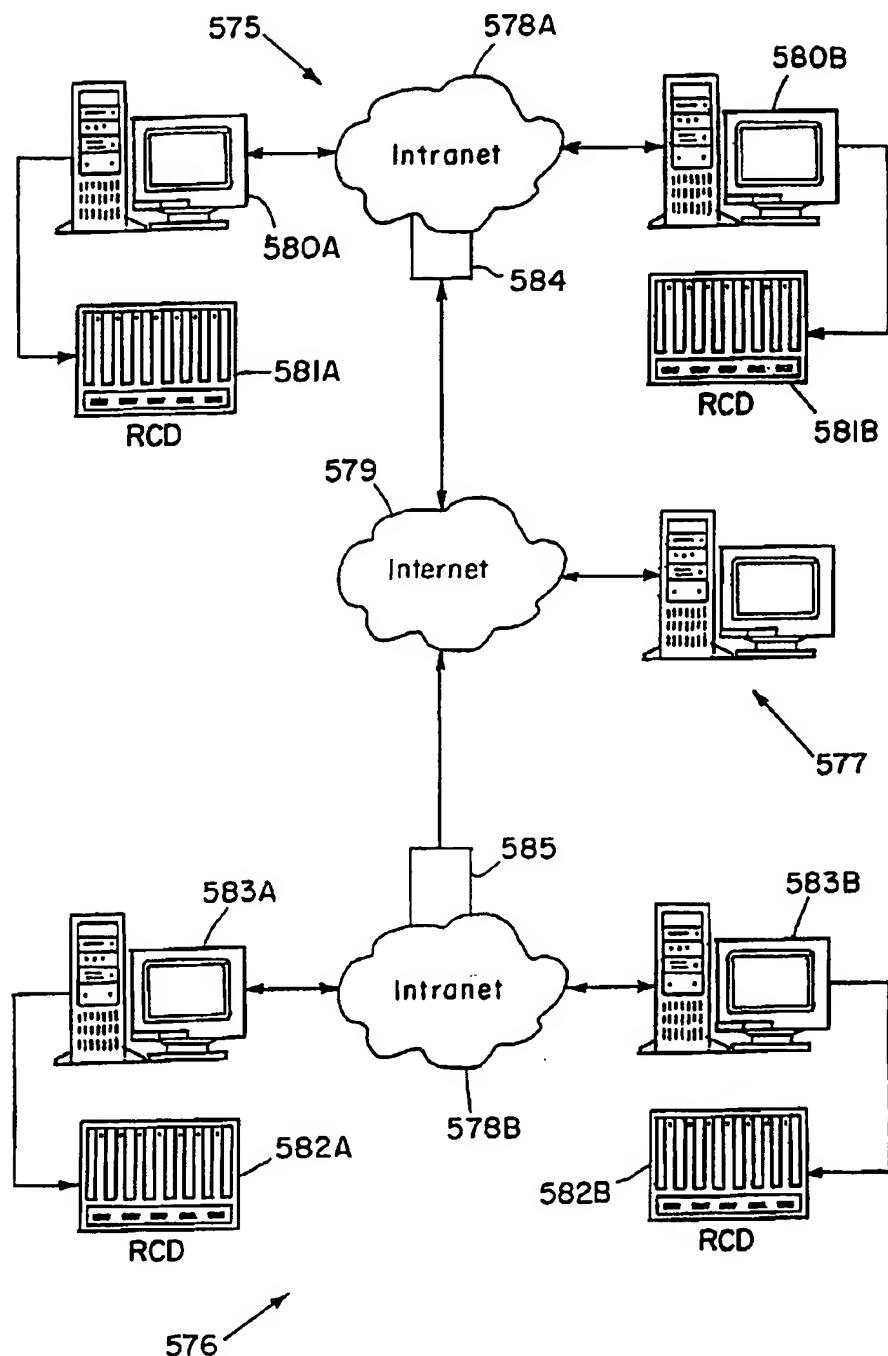


FIG. 18

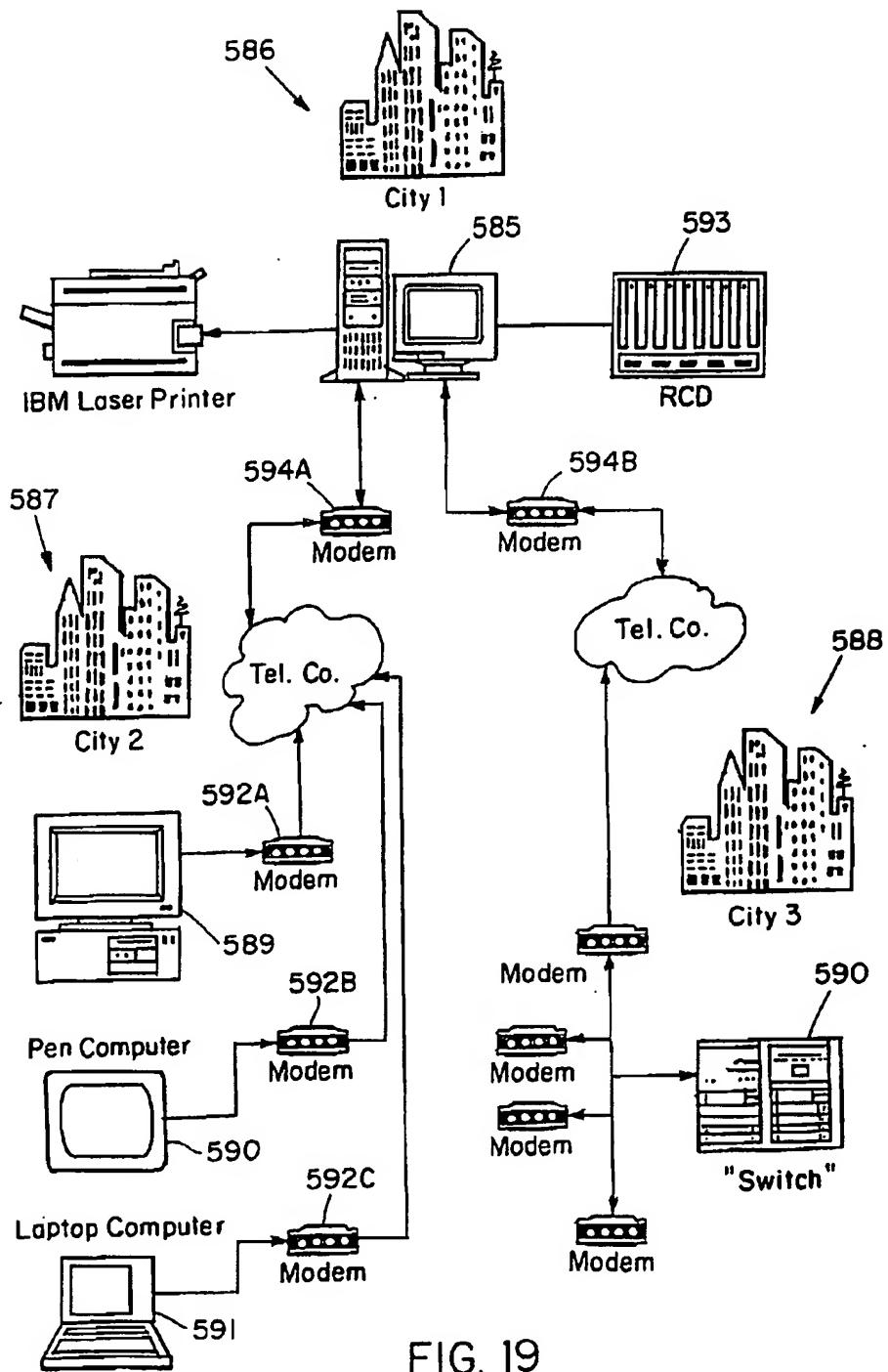


FIG. 19

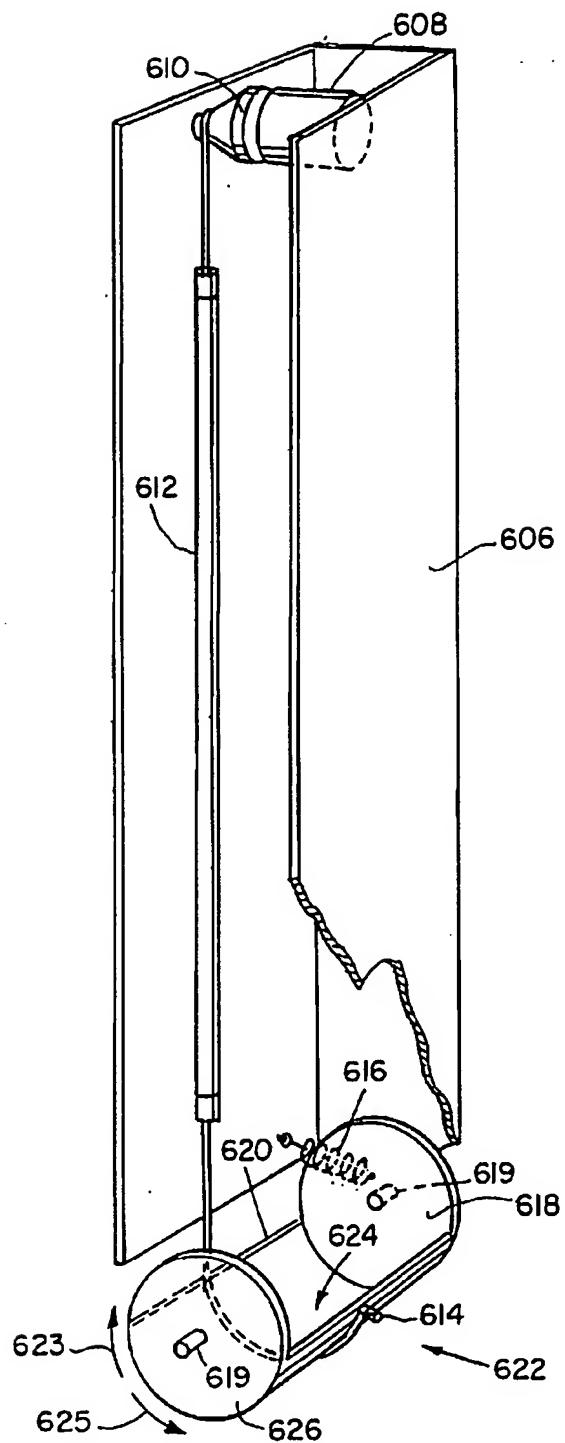


FIG. 20

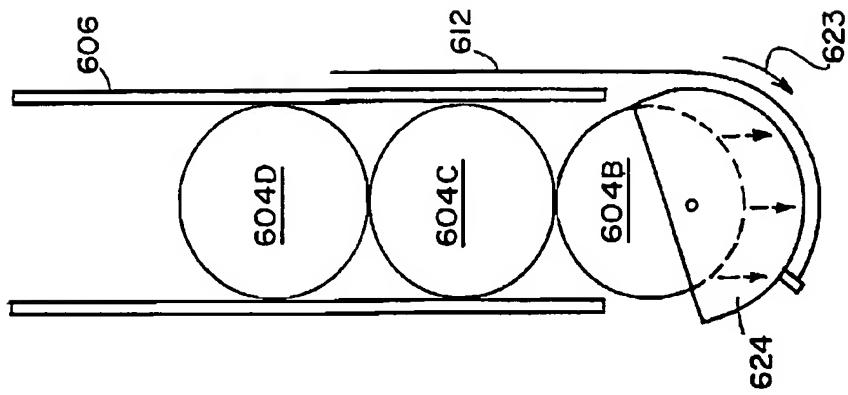


FIG. 21C

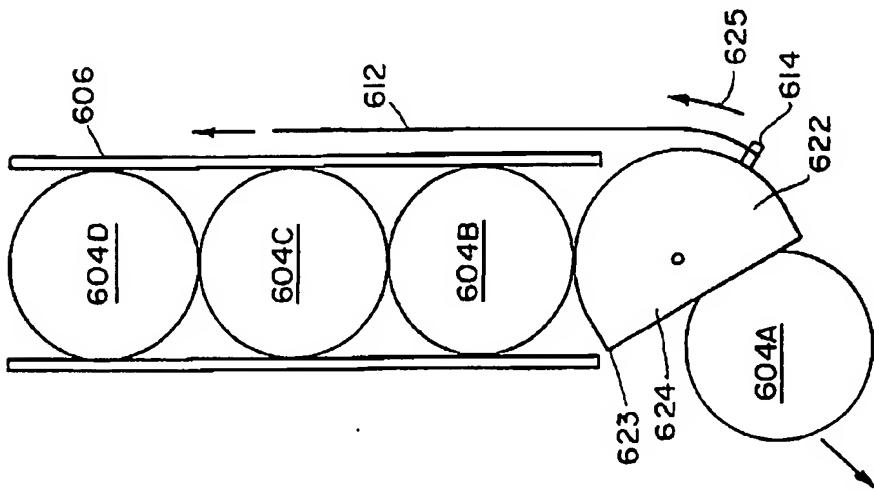


FIG. 21B

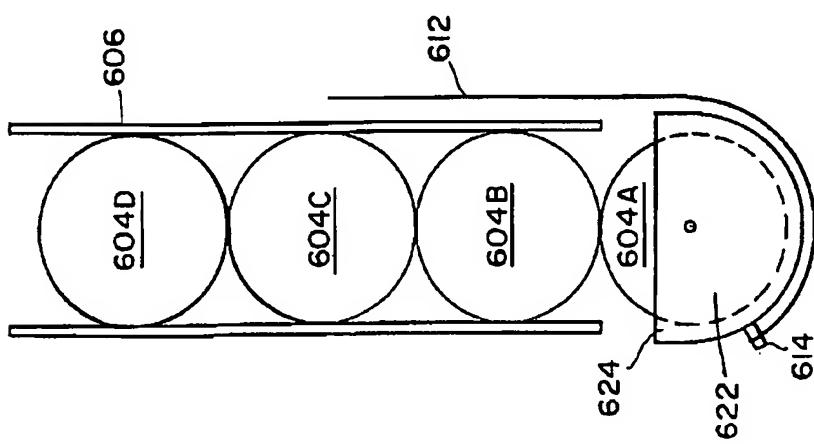
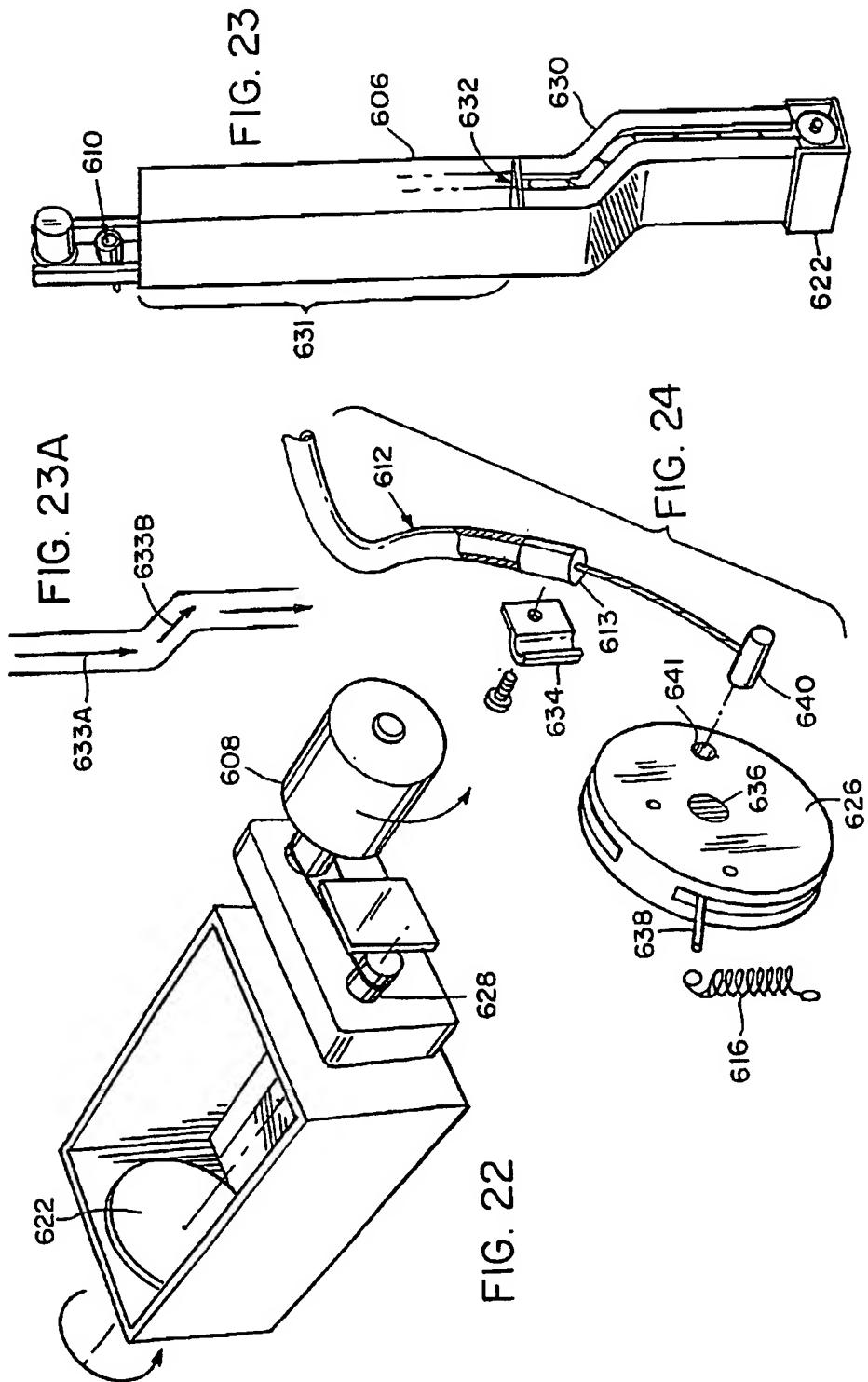
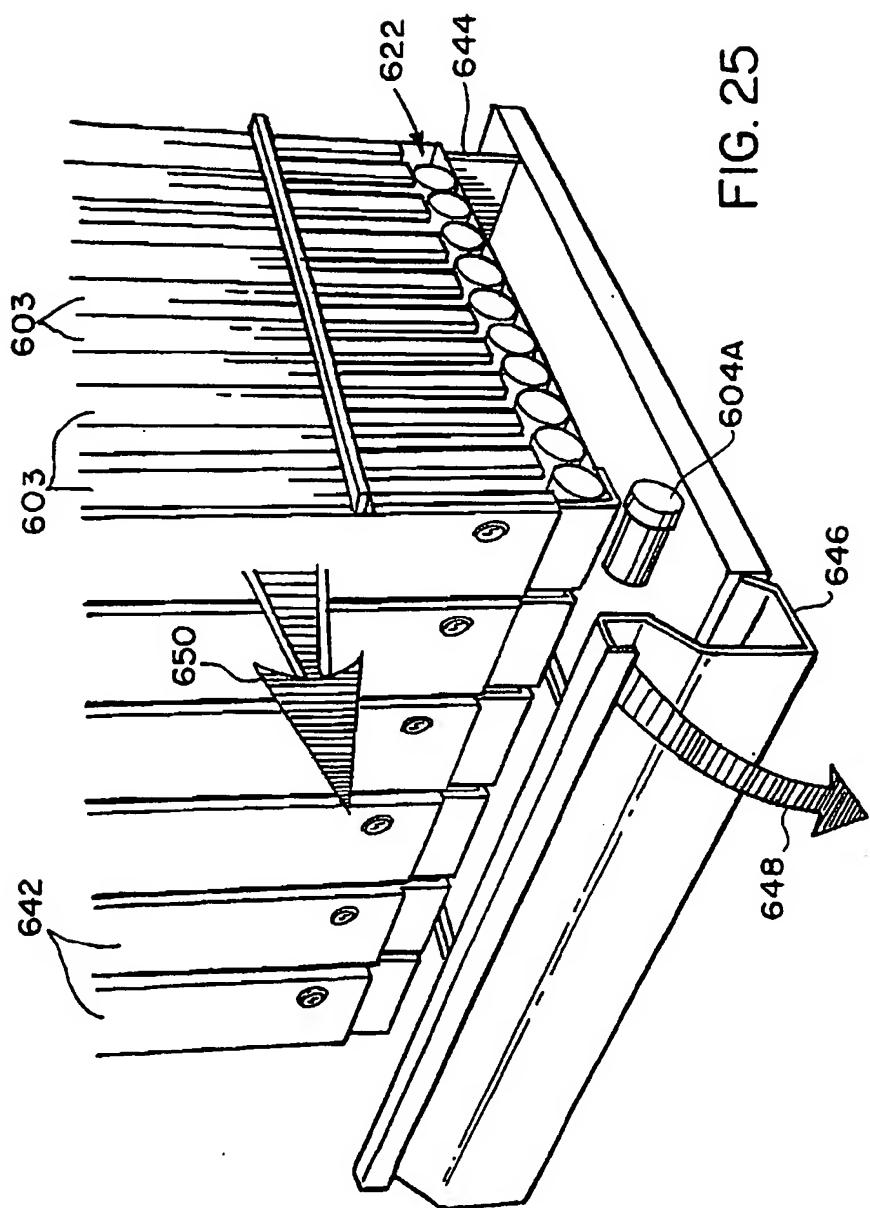
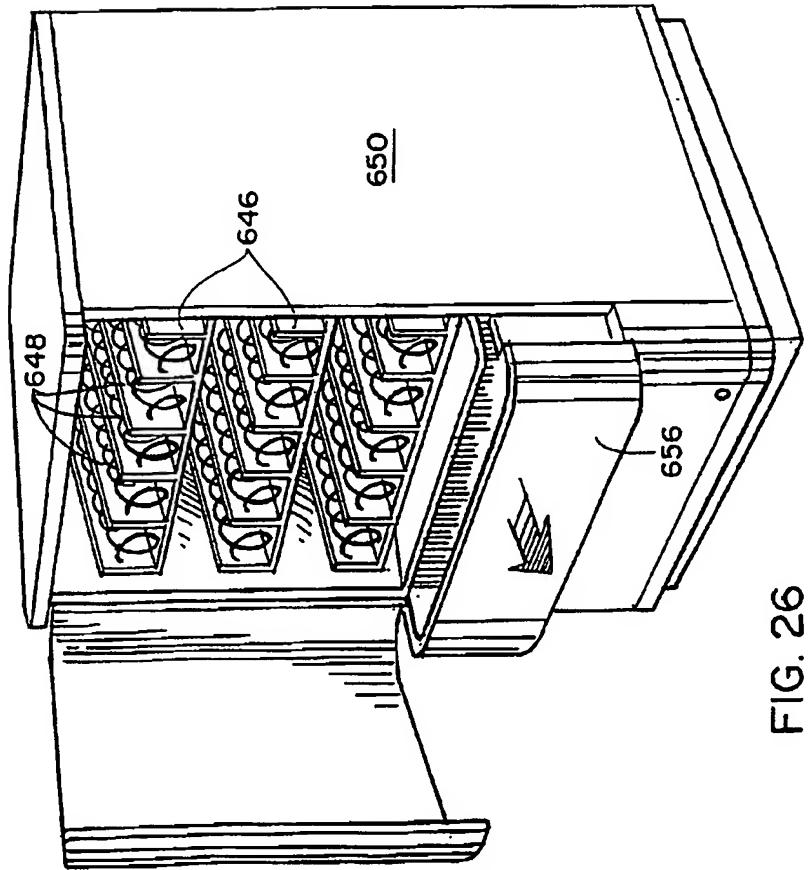
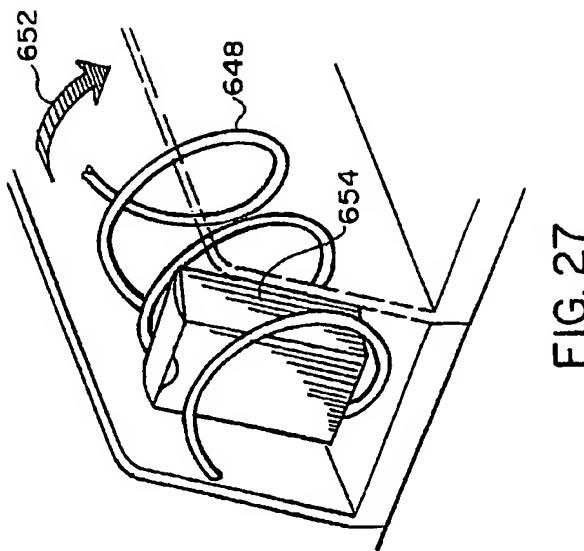


FIG. 21A







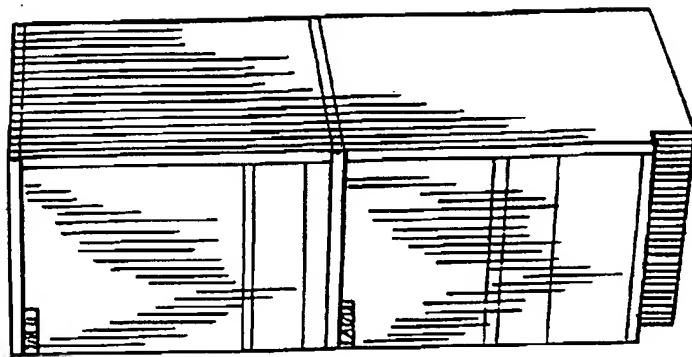


FIG. 29

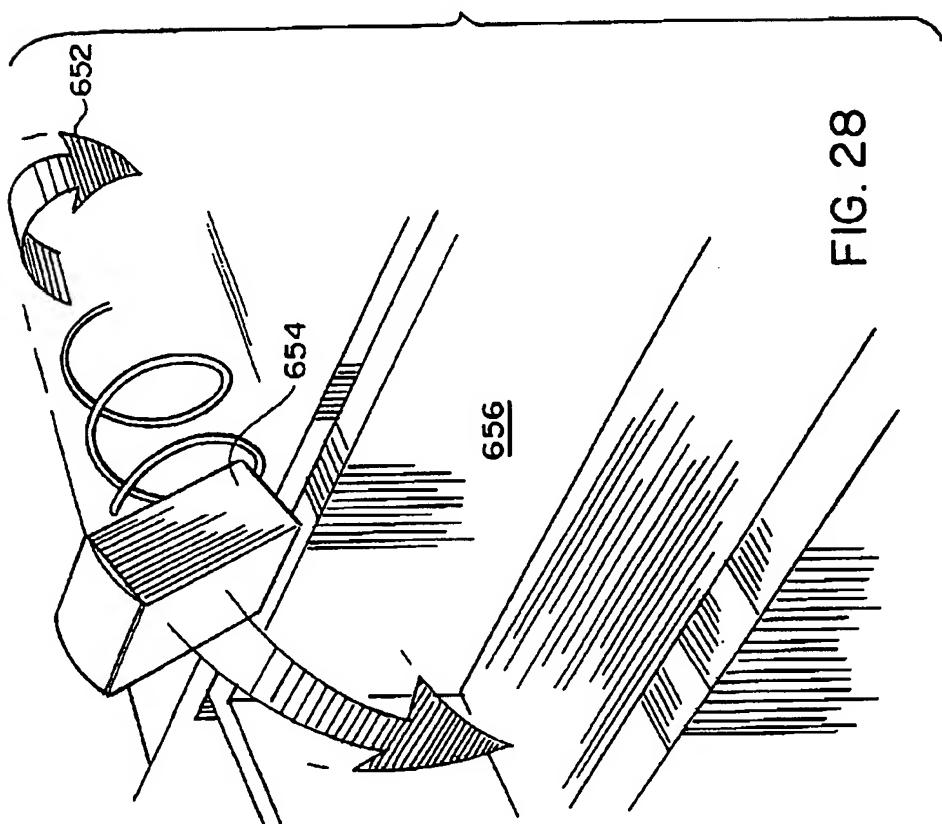


FIG. 28

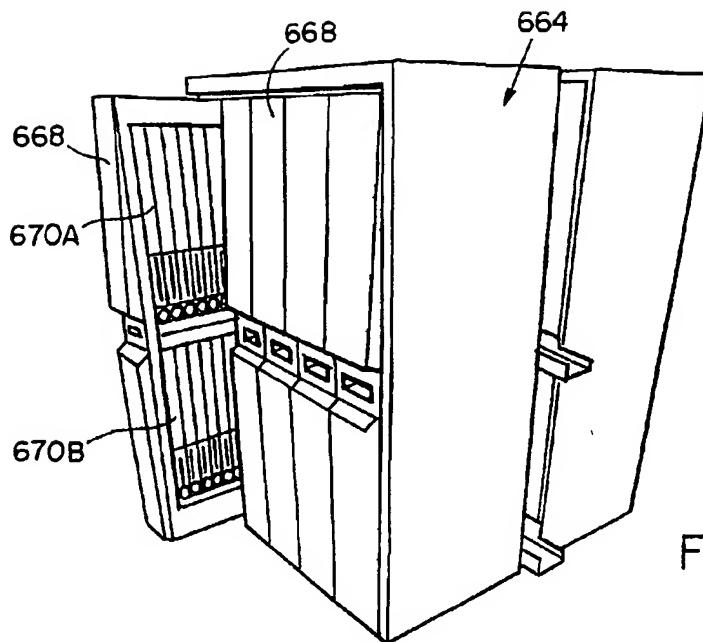


FIG. 30

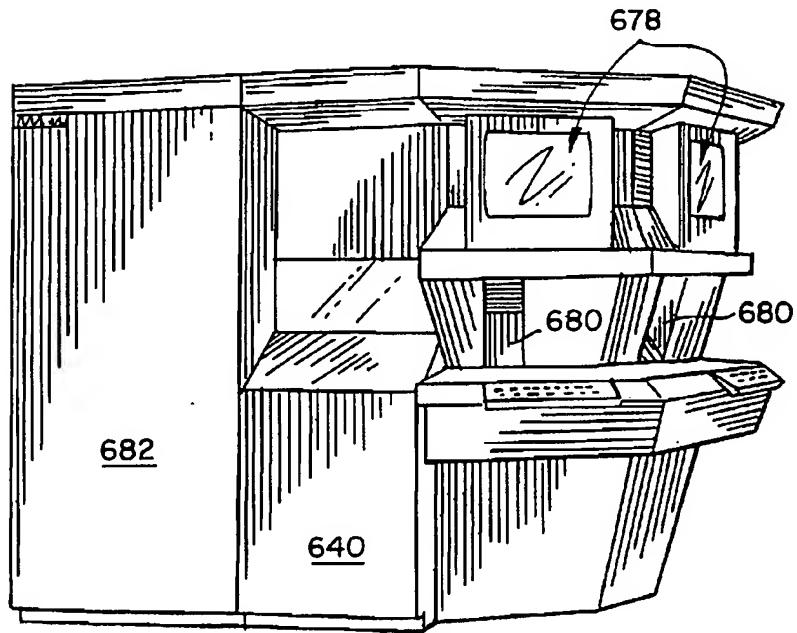


FIG. 32

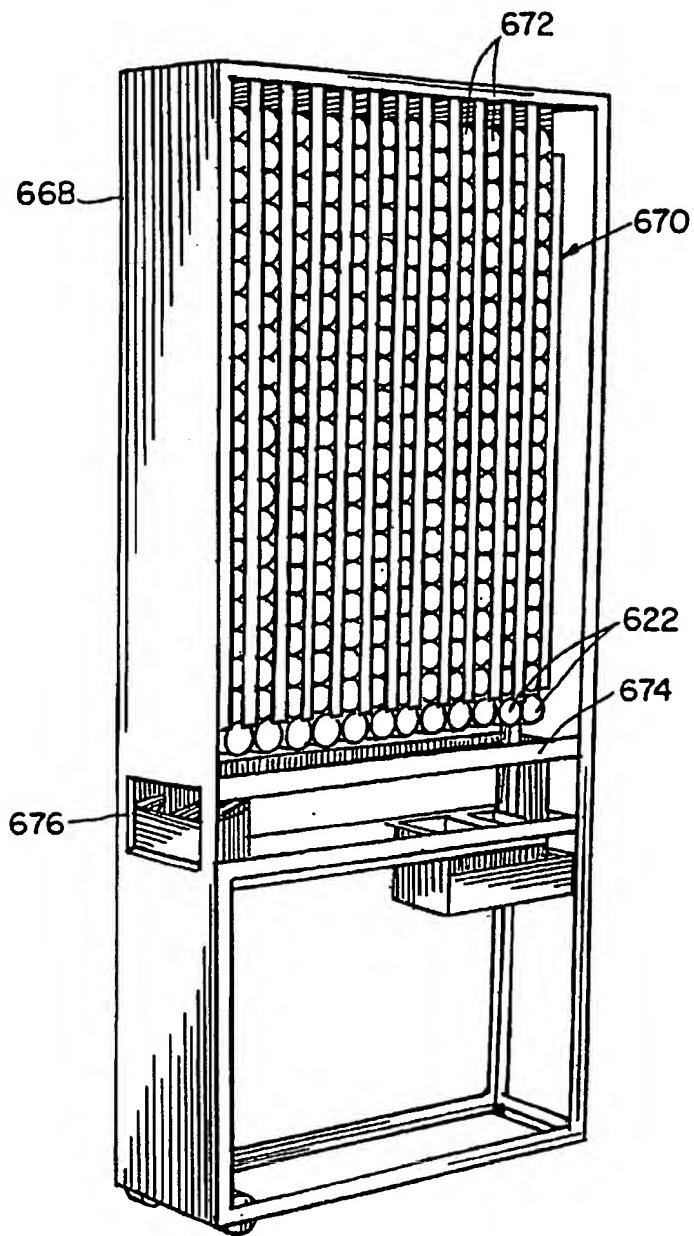


FIG. 31

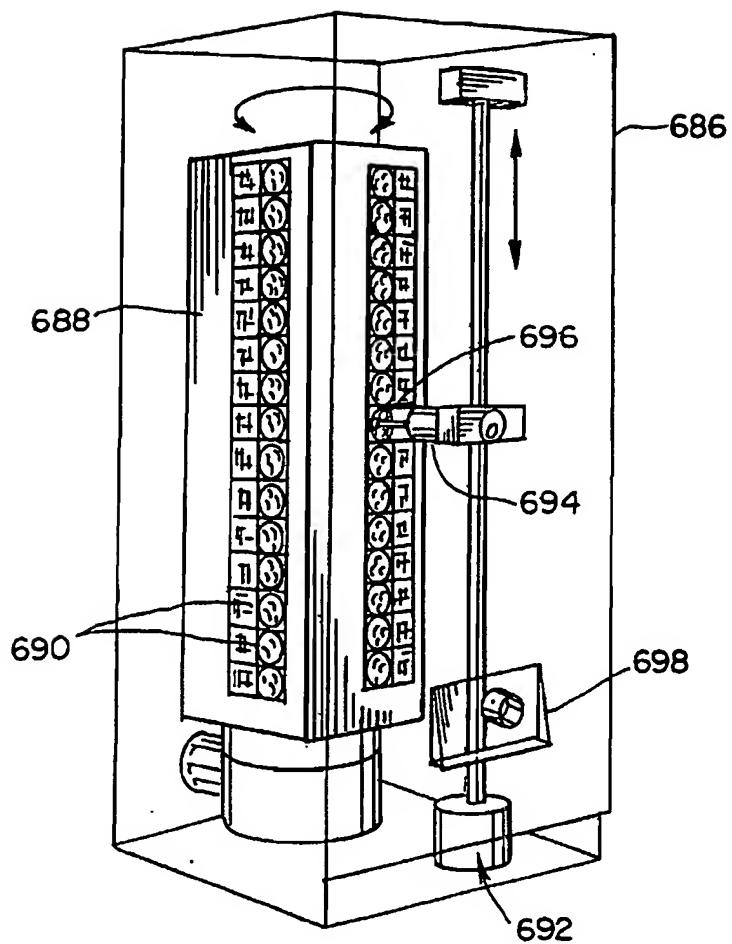


FIG. 33



(19) Europäisches Patentamt  
European Patent Office  
Office européen des brevets



(11) EP 1 041 529 A1

(12) EUROPEAN PATENT APPLICATION  
published in accordance with Art. 158(3) EPC

(43) Date of publication:  
04.10.2000 Bulletin 2000/40

(51) Int. Cl. 7: G09F 3/02

(21) Application number: 99943420.2

(86) International application number:  
PCT/JP99/05113

(22) Date of filing: 20.09.1999

(87) International publication number:  
WO 00/17839 (30.03.2000 Gazette 2000/13)

(84) Designated Contracting States:  
AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU  
MC NL PT SE

(72) Inventors:  
• YAMANAKA, Masaaki  
Oji-Yuka Synth. Paper Co., Ltd.  
Kashima-gun Ibaraki 311-1400 (JP)  
• HIRANO, Kazumasa  
Oji-Yuka Synth. Paper Co., Ltd.  
Kashima-gun Ibaraki 311-1400 (JP)

(30) Priority: 22.09.1998 JP 26849898

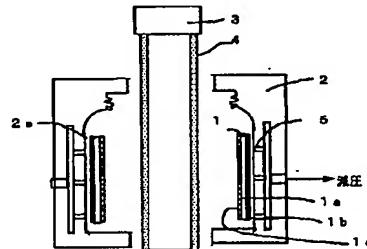
(74) Representative:  
VOSSIUS & PARTNER  
Siebertstrasse 4  
81675 München (DE)

(71) Applicant:  
Oji-Yuka Synthetic Paper Co. Ltd.  
Tokyo 101-0062 (JP)

(54) TRANSPARENT LABEL

(57) Disclosed is a transparent film comprising a substrate layer (A) of a uniaxially stretched film containing 95 to 100 wt% of thermoplastic resin and 0 to 5 wt% of an inorganic or organic fine powder having an average particle size of 0.2 to 2  $\mu$ m, a surface layer (B) of a uniaxially stretched film containing 85 to 99 wt% of a thermoplastic resin and 1 to 15 wt% of an inorganic fine powder having an average particle size of 0.7 to 3  $\mu$ m and being provided on one surface of the substrate layer (A), and an adhesive layer (C) of a uniaxially stretched film containing 90 to 99 wt% of a thermoplastic resin having a melting point of 80 to 140°C and containing 1 to 10 wt% of an inorganic or organic fine powder having an average particle size of 0.7 to 3  $\mu$ m and being provided on the other surface of the substrate layer (A). The transparent label is characterized in that having an excellent transparency and suitability for in-mold forming.

Fig. 1



EP 1 041 529 A1

**Description**

**Technical Field**

5 [0001] The present invention relates to a transparent label suitable for in-mold forming and method for fabricating thereof.

**Background Art**

10 [0002] The in-mold forming method is known as a method for fabricating, by integral molding, a synthetic resin formed product originally attached with a label. In this method, a label is first placed on the inner wall of the metal mold, and then a forming resin such as polyethylene and polypropylene is directly fed into the metal mold to obtain a formed product by injection molding, hollow molding or in-mold bead foaming. For the case of attaching a label onto polypropylene or polyethylene sheet, the attachment can be effected based on the same principle by a method such as that 15 promoting forming based on differential pressure under heating of the sheet (vacuum molding, differential pressure molding).

[0003] A variety of transparent labels have been proposed as available for such in-mold forming. An exemplary transparent label is that obtained by coating on a substrate layer a solution of low-melting-point olefin resins such as ethylene-vinyl acetate copolymer using a gravure coater or the like and by successive drying; where the substrate layer comprises a non-stretched extruded film made of crystalline polypropylene or high-density polyethylene, or a transparent film formed by the calendar process. There are also proposed films such that fabricated by stacking a low-melting-point olefin base resin film on one surface of the substrate layer using an adhesive or by direct extrusion lamination.

[0004] This attached label, however, is less attractive in that lacking gross and quality sense since the film comprising the substrate layer is of non-stretched type. Another problem is that the film may easily be stretched due to tensile force when it is subjected to gravure printing in a wound-up state, which may result in misalignment of patterns and prevent high-definition printing. Still another problem is that crimping of the film due to lack of its stiffness, which is likely to occur when the label cut into a predetermined size is attached to the inner wall of the metal mold using a robot inserter, so that high-speed attachment of the film will result into failure. Moreover, a label coated or laminated with an adhesive layer requires excessive process steps and, as a result, higher production cost.

[0005] On the other hand, as a transparent label for overcoming the foregoing drawbacks, proposed is a label which is fabricated by laminating low-melting-point olefin resin such as a low-density polyethylene or ethylene-vinyl acetate copolymer on a substrate layer comprising a sheet of longitudinally stretched crystalline polypropylene, and by transversely stretching the laminate using a tenter oven. Decorating polyethylene using such label by hollow molding, however, requires a parison temperature of 180°C or above and a metal mold cooling temperature or 30°C or above. As for hollow molding of polypropylene, a satisfactory product also cannot be obtained unless the parison temperature is raised as high as 230°C or above and the metal mold cooling temperature is as high as 30°C or above. Conditions out of the above ranges will result in generation of blisters which lowers the adhesive strength of the label and prevents practical products from being produced.

[0006] To ensure high-speed and low-cost hollow molding of polyethylene (m.p. 108-135°C) containers, it is desirable in general to lower the parison temperature as possible and shorten the cooling period thereby to shorten the forming cycle. Whereas, treating a transparent label having a substrate layer made of a biaxially stretched film or non-stretched film at the above required temperatures will weaken the adhesive strength of the label to cause blisters, and will fail in obtaining practical products.

[0007] For addressing the above problems in the prior art, it is therefore an object of the present invention to provide a transparent label suitable for in-mold forming. That is, the present invention is aimed at obtaining a transparent label excellent in transparency, smoothness of an adhesive layer, Clark stiffness, label attachment property, blister suppressing property after in-mold forming and label adhesive property. It is another object of the present invention to provide a simple and low-cost method for fabricating such a transparent label.

50 **Description of the Invention**

[0008] The present inventors found after extensive investigations for solving the foregoing problems that a transparent film can be attached without any problem by in-mold forming by using a label comprising a substrate layer (A) of a uniaxially stretched film, a surface layer (B) of a uniaxially stretched film, and an adhesive layer (C) of a uniaxially stretched film, each layer having a specific composition, which led us to provide the present invention.

[0009] Thus, the present invention provides a transparent film comprising a substrate layer (A) of a uniaxially stretched film containing 95 to 100 wt% of thermoplastic resin and 0 to 5 wt% of an inorganic or organic fine powder having an average particle size of 0.2 to 2 µm, a surface layer (B) of a uniaxially stretched film containing 85 to 99 wt%

of a thermoplastic resin and 1 to 15 wt% of an inorganic fine powder having an average particle size of 0.7 to 3  $\mu$ m and is provided on one surface of the substrate layer (A), and an adhesive layer (C) of a uniaxially stretched film containing 90 to 99 wt% of a thermoplastic resin having a melting point of 80 to 140°C and containing 1 to 10 wt% of an inorganic or organic fine powder having an average particle size of 0.7 to 3  $\mu$ m and being provided on the other surface of the substrate layer (A).

[0010] In a preferred embodiment of the present invention, the substrate layer (A), surface layer (B) and adhesive layer (C) comprise a film uniaxially stretched by 2 to 8 times. The thermoplastic resin employed herein preferably contains polyolefin resin. The transparent label of the present invention preferably has a longitudinal Clark stiffness of 30 to 250, a transverse Clark stiffness of 10 to 50, an opacity of 20% or below, and a smoothness of the adhesive layer (C) of 100 to 2,500 seconds. The total thickness of the label is preferably 60 to 250  $\mu$ m, and a thickness of the surface layer (B) and adhesive layer (C) is 1 to 10  $\mu$ m, respectively. The adhesive layer is preferably embossed.

[0011] The present invention also provides a method for fabricating a transparent film comprising the steps of: forming, on one side of a substrate layer (A) a surface layer (B) of a uniaxially stretched film containing 85 to 99 wt% of a thermoplastic resin and 1 to 15 wt% of an inorganic fine powder having an average particle size of 0.7 to 3  $\mu$ m; the substrate layer (A) being made of a uniaxially stretched film containing 95 to 100 wt% of thermoplastic resin and 0 to 5 wt% of an inorganic or organic fine powder having an average particle size of 0.2 to 2  $\mu$ m; forming, on the other surface of the substrate layer (A), an adhesive layer (C) of a uniaxially stretched film containing 90 to 99 wt% of a thermoplastic resin having a melting point of 80 to 140°C and containing 1 to 10 wt% of an inorganic or organic fine powder having an average particle size of 0.7 to 3  $\mu$ m; and uniaxially stretching the obtained laminate. The uniaxial stretching is preferably effected by 2 to 8 times based on the difference in the peripheral speeds between the roll groups. Embossing of the adhesive layer (C) preferably precedes the uniaxial stretching.

[0012] The above and other objects and features of the invention are apparent to those skilled in the art from the following referred embodiments thereof when considered in conjunction with the accompanied drawing, in which:

25 Fig. 1 is a sectional view of a forming apparatus used for producing a label-attached, hollow-formed container. In the figure, numeral 1 denotes a label, 1a denotes a substrate layer, 1b denotes a surface layer, 1c denotes an adhesive layer, 2 denotes a metal mold, 2a denotes an inner wall of the metal mold, 3 denotes a die, 4 denotes a parison and 5 denotes a suction hole.

### 30 Detailed Description of the Invention

[0013] The transparent film of the present invention is characterized in that having a surface layer (B) on one side of the substrate layer (A), and having an adhesive layer (C) on the other side thereof. All of these substrate layer (A), surface layer (B) and adhesive layer (C) individually comprise a uniaxially stretched sheet which contains thermoplastic resin, inorganic fine powder or organic fine powder with a specific composition.

[0014] There is no special limitation on the kinds of the thermoplastic resin used for the substrate layer (A) and surface layer (B) and examples of which include polyolefin resins; polyamide resins such as nylon-6, nylon-6,6 and nylon-12; thermoplastic polyester resins such as polyethylene terephthalate and its copolymer, polybutylene terephthalate and its copolymer, and aliphatic polyester; polycarbonate; atactic polystyrene; and syndiotactic polystyrene. Among these, non-polar polyolefin resins are preferably used.

[0015] Representative examples of the polyolefin resins include homopolymer of  $\alpha$ -olefin having a carbon number of 2 to 8 such as ethylene, propylene, 1-butene, 1-hexene, 1-heptene, 1-octene, 4-methyl-1-pentene and 3-methyl-1-pentene; and copolymer of 2 to 5 species selected from such  $\alpha$ -olefins.

[0016] Either random copolymer or block copolymer is allowable. More specifically, allowable are branched or normal polyethylene having a density of 0.89 to 0.97 g/cm<sup>3</sup> and a melt flow rate (190°C, 2.16 kg load) of 1 to 10 g/10 minutes; propylene homopolymer having a melt flow rate (230°C, 2.16 kg load) of 0.2 to 15 g/10 minutes; propylene-ethylene copolymer; propylene-(1-butene) copolymer; propylene-ethylene-(1-butene) copolymer; propylene-(4-methyl-1-pentene) copolymer or propylene-(4-methyl-1-pentene) copolymer. Among these, propylene homopolymer, propylene-ethylene copolymer and high-density polyethylene are preferable in terms of inexpensiveness and good forming property.

[0017] While there is no specific limitation on the kinds of the thermoplastic resin used for the adhesive layer (C), it is preferable to use that having a melting point of 80 to 140°C.

[0018] For example, available are polyolefin resins such as propylene-ethylene copolymer, high-density polyethylene, middle-density polyethylene, low-density polyethylene, ethylene-vinyl acetate copolymer, ethylene-acrylic ester copolymer, ethylene-methacrylic ester copolymer, ethylene- $\alpha$ -olefin copolymer and metal salts thereof. Among these, preferable are ethylene-base resins such as ethylene-acrylic ester copolymer, ethylene-vinyl acetate copolymer and ethylene- $\alpha$ -olefin copolymer.

[0019] For the substrate layer (A), surface layer (B) or adhesive layer (C), one kind of the thermoplastic resin may

be selected from those listed above to be used individually, or two or more thereof may be selected to be used in combination. In particular for the case that two or more thereof are used in combination for the adhesive layer (C), it is preferable to use them so that an average melting point, estimated using melting points of individual compound resins and based on the blend ratio by weight thereof, will fall within a range from 80 to 140°C. Either the same resins or different resins can be used for the substrate layer (A), surface layer (B) and adhesive layer (C). Kinds of the thermoplastic resins can properly be selected depending on specific properties required for the individual layers.

5 [0020] There is no special limitation on the kinds of inorganic or organic fine powders used for the substrate layer (A), surface layer (B) and adhesive layer (C).

10 [0021] Examples of the inorganic fine powder include heavy calcium carbonate, precipitated calcium carbonate, fired clay, talc, barium sulfate, diatom earth, magnesium oxide, zinc oxide, titanium oxide and silicon oxide. Among these, heavy calcium carbonate, fired clay and talc are preferable in terms of inexpensiveness and forming property.

15 [0022] Examples of the organic fine powder include those made of polyethylene terephthalate, polybutylene terephthalate, polyamide, polycarbonate, polyethylene naphthalate, polystyrene, melamine resin, polyethylene sulfite, polyimide, polyethyl ether ketone and polyphenylene sulfite. Among these preferably used are such that having a higher melting point than that of the thermoplastic resin employed, and having non-compatibility.

20 [0023] For the substrate layer (A), surface layer (B) or adhesive layer (C), one kind of the fine powder may be selected from those listed above to be used individually, or two or more thereof may be selected to be used in combination. For the case that two or more thereof are used in combination for the substrate layer (A) or adhesive layer (C), it is allowable to mix the inorganic and organic fine powders.

25 [0024] Either the same resins or different resins can be used for the substrate layer (A), surface layer (B) and adhesive layer (C), provided that the average particle size must be within a range from 0.2 to 2  $\mu\text{m}$  for the substrate layer (A), and from 0.7 to 3  $\mu\text{m}$  for the surface layer (B) and adhesive layer (C). Selecting an average particle size of the fine powder for the substrate layer (A) within the above range will ensure the opacity of the obtained label fall to 20% or below. Selecting an average particle size of the fine powder for the surface layer (B) and adhesive layer (C) within the above range will successfully provide fine cracks or emboss on the surface thereof to improve adhesive property of printing ink and slipping property of the label, and, in particular for the adhesive layer, will prevent an air reservoir (blister) from being generated between the formed product and the label during in-mold forming. As for the surface layer (B), it is preferable to suppress a content of larger particles of 44  $\mu\text{m}$  diameter or above to 10 ppm or below, since such particles can form rough projections causative of white spots during printing.

30 [0025] When fabricating the transparent label of the present invention, the thermoplastic resin and the inorganic or organic fine powder are mixed to form individual layers. The transparent label of the present invention can be fabricated by any combination of various methods known to those skilled in the art. Any transparent label fabricated by any method is included within a scope of the present invention as far as it satisfies the conditions as defined in Claim 1.

35 [0026] Amounts of the thermoplastic resin and inorganic or organic fine powder used for individual layers are limited within specific ranges. For the substrate layer (A), the thermoplastic resin is compounded in an amount of 90 to 100 wt%, and inorganic or organic fine powder in an amount of 0 to 5 wt%. The fine powder exceeding 5 wt% will significantly reduce the transparency of the obtained label.

40 [0027] For the surface layer (B), the thermoplastic resin is compounded in an amount of 85 to 99 wt%, and inorganic fine powder in an amount of 1 to 15 wt%. The inorganic fine powder less than 1 wt% will ruin the adhesive property of the ink and slipping property of the label, whereas exceeding 15 wt% will reduce the transparency of the label while the adhesive property of the ink and slipping property of the label improve.

45 [0028] For the adhesive layer (C), the thermoplastic resin is compounded in an amount of 90 to 99 wt%, and inorganic or organic fine powder in an amount of 1 to 10 wt%. The fine powder less than 1 wt% will reduce the blister suppressing effect during in-mold forming due to an excessively smoothed surface, whereas exceeding 10 wt% will lower the adhesive strength of the in-mold formed label due to relative reduction in the resin component.

50 [0029] It is acceptable to optionally add a dispersant, antioxidant, solubilizing agent or ultraviolet stabilizer when compounding and kneading the thermoplastic resin with inorganic or organic fine powder. Composition for forming the individual layers obtained by the compounding and kneading can be formed into a layer by, for example, extrusion process, where the substrate layer (A), surface layer (B) and adhesive layer (C) may be stacked *en bloc* by co-extrusion process, or may be laminated after separately extruded. For the case of the separate extrusion, allowable is either process such that laminating the surface layer (B) on the substrate layer (A) and then laminating the adhesive layer (C), or such that laminating the adhesive layer (C) on the substrate layer (A) and then laminating the surface layer (B). It is still allowable to simultaneously laminate the substrate layer (A), surface layer (B) and adhesive layer (C). Moreover, allowable is either process such that the substrate layer (A) and surface layer (B) are co-extruded and then the adhesive layer (C) is laminated, or such that the substrate layer (A) and adhesive layer (C) are co-extruded and then the surface layer (B) is laminated.

55 [0030] Uniaxial stretching is essential for fabricating the transparent label of the present invention. The uniaxial stretching can be performed either before or after the lamination of the individual layers. It is thus acceptable to laminate

precedently stretched layers, or to stretch the laminate *en bloc* after the individual layers are laminated. Or, it is also allowable to laminate precedently stretched layers and to further stretch the laminate. A preferable fabrication method includes the steps of laminating the substrate layer (A), surface layer (B) and adhesive layer (C) and then stretching the laminate *en bloc*, which is simpler and cheaper as compared with the case of the separate stretching and successive lamination.

5 [0031] A variety of known methods is applicable to the stretching. Stretching temperature, for the case using a non-crystalline thermoplastic resin, can be set at a temperature equal to or higher than a glass transition point thereof; and, for the case using a crystalline resin, can be set within a temperature range from a glass transition point of the non-crystalline domain to the melting point of the crystalline domain, both inclusive.

10 [0032] While there is no special limitation of a method for the stretching, preferable is inter-roll stretching based on difference in the peripheral speeds between the roll groups. This method allows arbitrary selection of stretching times, thereby to afford a transparent film while extremely reducing void likely to generate during the stretching. Since stretching orientation of the resin occurs along the film feeding direction, so that obtained is a transparent label having a higher tensile strength and less dimensional changes due to tension during printing as compared with those of a non-stretched film.

15 [0033] The stretching times can be set within a range from 2 to 8. The stretching times less than 2 will lower the tensile strength along the film feeding direction, and thus cause large dimensional changes during printing and insufficient label stiffness. On the other hand, the stretching times exceeding 8 will result in a frequent breakage of the label during the stretching.

20 [0034] After the stretching, it is also allowable to optionally perform high temperature anneal using heating rolls to effect thermosetting.

25 [0035] The total thickness of the transparent label of the present invention is preferably 60 to 250  $\mu\text{m}$ , where the total thickness of the label less than 60  $\mu\text{m}$  will increase the dimensional changes during printing and likely to cause color misalignment during multi-color printing. Such label may degrade its attaching property during high-speed in-mold forming so that in some cases the speed of in-mold forming must inevitably be slowed down. The total label thickness exceeding 250  $\mu\text{m}$  will increase morphological changes in the in-mold formed products and tends to make it difficult to obtain containers of a desired capacity.

30 [0036] Thicknesses of the surface layer (B) and adhesive layer (C) are preferably 1 to 10  $\mu\text{m}$ , respectively. A thickness of the surface layer (B) less than 1  $\mu\text{m}$  tends to degrade printing suitability of the surface layer (B), and a thickness of the adhesive layer (C) less than 1  $\mu\text{m}$  tends to degrade the adhesion strength. Thicknesses of the surface layer (B) and adhesive layer (C) exceeding 10  $\mu\text{m}$  tend to lower Clark stiffness or to degrade the transparency.

35 [0037] Printing to the surface layer (B) can be provided according to common methods. For example, pattern, bar code, character information, and scale can properly be printed by purpose of use. Methods for printing include gravure printing, offset printing, flexographic printing, screen printing and seal printing.

40 [0038] The transparent label of the present invention may be subjected to embossing finish. Embossing finish may precede printing although it generally follows printing. The transparent label of the present invention is preferably embossed before printing.

45 [0039] While there is no specific limitation on the method of embossing finish, it is enabled by known press or embossing machine such as a planographic press machine or roll embossing machine by which surface irregularity is produced on an embossing plate by thermocompression. Roll embossing process refers to a method for transferring surface irregularity of a cylindrical embossing plate onto a target material by thermocompression. The thermocompressive transfer can be effected by heating the transparent label to a temperature between the heat deformation temperature and fusing temperature of the resin used in the adhesive layer (C), and then pressing an embossing plate onto the surface of the stretched film made of the thermoplastic resin. Methods for heating include infrared irradiation, hot air blowing, heat conduction mediated by a heating roller and dielectric heating. The embossing using an embossing roll can be performed either before or after the stretching, and also simultaneously with the film forming.

50 [0040] An emboss pattern has 5 to 200 dots or lines per one inch, and more preferably 15 to 120. Depth of a concave of the emboss pattern is 1/3 or more of the thickness of the adhesive layer (C), and more preferably 1/2 or more, where the concave reaching and intruding the substrate layer (A) also being allowable.

55 [0041] The transparent label of the present invention preferably has an opacity of 20% or below. The term "opacity" used in a context of this specification means that measured in accordance with JIS (Japanese Industrial Standard) Z-8722. The opacity of 20% or below allows the surface of the formed product to be seen clearly through the label. This ensures an integrated appearance of the non-printed transparent portion of the label and the surface of the formed product and can successfully upgrade a quality image of the product. In particular for the formed product having on the surface of which a characteristic pattern or coloring, such label is aesthetically advantageous since it will not affect the original pattern nor coloring. For the case of fabricating a transparent container, such label is convenient since the contents in the container can be seen through the attached label. For example, attachment of a label printed with a scale will be convenient to easily check the amount of contents in the container.

[0042] Smoothness of the adhesive layer (C) of the transparent label according to the present invention is preferably within a range from 100 to 2,500 seconds. The term "smoothness" in a context of this specification means that measured in accordance with JIS P-8119. The smoothness of less than 100 seconds tends to reduce a label attachment area, which will result into failure in obtaining a sufficient adhesive strength durable in the practical use. Whereas 5 the smoothness exceeding 2,500 seconds tends to produce blister due to air reserved between a parison and label adhesion surface during in-mold forming.

[0043] The Clark stiffness of the transparent label of the present invention is preferably 30 to 250 in the longitudinal direction and 10 to 50 in the transverse direction. The term "Clark stiffness" in a context of this specification means "S" value measured in accordance with JIS P-8143.

10 [0044] If the transversal Clark stiffness is less than 10, the label tends to crimp or dislocate during robot-assisted placement thereof to a predetermined position in the a metal mold, which prevents the label from being correctly attached. Whereas, if the longitudinal Clark stiffness exceeds 250, the label tends to float up from the curved wall surface of the metal mold, thereby to cause drop of the label from the metal mold or significant decrease in the adhesive force between a formed product and the label, which may result in blister generation.

15 [0045] It is recommendable to make the longitudinal direction of the label and trailing direction of the parison coincide with each other. Label attachment property, label adhesive property and anti-blister property will be improved by aligning the parison trailing direction to a direction of higher stiffness of the label, and aligning a direction normal to the parison trailing direction to a direction of lower stiffness.

20 [0046] The transparent label of the present invention is in particular suitable for in-mold forming. In-mold forming using the transparent label of the present invention can be performed according to the common practice. For example, it is possible to directly feed a forming resin into a metal mold, on the inner wall of which the transparent label of the present invention being already placed, and to perform injection molding, hollow molding or in-mold bead foaming. The label is placed so that the surface layer (B) of which comes into contact with the inner wall of the metal mold. The label can be placed by vacuum suction through the holes opened on the inner wall of the metal mold.

25 [0047] There is no specific limitation on the forming resin fed into the metal mold, and can properly be selected depending on target applications, conditions of use and structures of the formed products. Examples of such resin include high-density polyethylene, low-density polyethylene, polypropylene, nylon-6, nylon-6,6, polyethylene terephthalate, polycarbonate, polyphenylene oxide, polyphenylene ether and ethylene-vinyl acetate copolymer.

30 [0048] For the case of forming by hollow forming process, heated parison of a forming resin is trailed, one end of which is fused by fastening the metal mold, a compressed gas is introduced into the parison and allow it to expand. The parison is pressed to the inner wall of the metal mold to be formed into a shape conforming to the metal mold and, in association with this, the adhesive layer (C) of the transparent label is fused thereon. After cooling, the metal mold is opened to release a mold product attached with the transparent label.

35 [0049] For the case of forming by differential pressure molding, at least either of vacuum molding or compressed air molding is applicable. A combined use of vacuum and compressed air moldings is preferable in general, in particular with the aid of plug assisting.

40 [0050] The transparent label of the present invention also allows heat sealing in accordance with a known methods besides in-mold forming, since the label uses on the rear surface thereof a low-melting-point adhesive resin. Thus the transparent label of the present invention is versatile also as a wrapping material and header label. The transparent label of the present invention can beneficially be used in a wide variety of applications.

45 [0051] In the paragraphs below, the present invention will further be detailed referring to Comparative Examples and Examples. Materials, amounts of uses, ratios and operations mentioned hereinafter can be altered without departing from the spirit of the present invention, and thus it should be understood that the scope of the present invention is not limited to the specific Examples shown below.

[0052] Materials used in the Example and Comparative Example are listed in Table 1.

Table 1

50	Materials	Description
	Polyolefin (a)	propylene homopolymer, m.p. 164°C (DSC peak temperature)(product of Mitsubishi Chemical Corporation)
55	Polyolefin (b)	ethylene-propylene copolymer, m.p. 142°C (DSC peak temperature)(product of Mitsubishi Chemical Corporation)
	Polyolefin (c)	high-density polyethylene, m.p. 134°C (DSC peak temperature)(product of Mitsubishi Chemical Corporation)

Table 1 (continued)

Materials	Description
Polyolefin (d)	linear low-density polyethylene, m.p. 128°C (DSC peak temperature)(product of Mitsubishi Chemical Corporation)
Polyolefin (e)	low-density polyethylene, m.p. 108°C (DSC peak temperature)(product of Mitsubishi Chemical Corporation)
Polyolefin (f)	ethylene-(1-hexene) copolymer, m.p. 100°C (DSC peak temperature)(product of Nihon Polychem Co., Ltd.)
Inorganic fine powder (a)	wet-ground heavy calcium carbonate, average particle size = 0.4 $\mu\text{m}$ (product of Phimatech Co., Ltd.)
Inorganic fine powder (b)	wet-ground heavy calcium carbonate, average particle size = 0.8 $\mu\text{m}$ (product of Phimatech Co., Ltd.)
Inorganic fine powder (c)	dry-ground heavy calcium carbonate, average particle size = 1.8 $\mu\text{m}$ (product of Shiroishi Calcium Co., Ltd.)
Inorganic fine powder (d)	dry-ground heavy calcium carbonate, average particle size = 2.8 $\mu\text{m}$ (product of Shiroishi Calcium Co., Ltd.)
Inorganic fine powder (e)	wet-ground heavy calcium carbonate, average particle size = 3.3 $\mu\text{m}$ (product of Shiroishi Calcium Co., Ltd.)
Inorganic fine powder (f)	synthetic calcium carbonate(colloidal calcium carbonate), average particle size = 0.15 $\mu\text{m}$ (product of Shiroishi Kogyo K.K.)

(Example and Comparative Example)

[0053] The transparent labels of the present invention (Examples 1 to 9) and comparative transparent labels (Comparative Examples 1 to 4) were fabricated according to the procedures described below. Types and amount of use of the materials employed, thicknesses of the individual layers (A)/(B)/(C), stretching conditions and stretching property were listed in Table 2.

[0054] Polyolefin-base resin and inorganic fine powder were mixed to obtain compounds [A], [B] and [C]. The compounds [A], [B] and [C] were separately fused and kneaded using three extruders conditioned at 230°C, 230°C and 180°C, respectively, the compounds [B] and [C] were then laminated within the die on the front and rear surfaces of the compound [A], respectively, the obtained laminate was extruded, cooled to 70°C, thereby to obtain a three-layered non-stretched sheet. The sheet was heated to a predetermined temperature and then longitudinally stretched by predetermined times by the inter-roll stretching process. In Examples 8 and 9, the sheets were, in advance of the stretching, passed through the embossing rolls comprising a metal roll and rubber roll to emboss dots of 50  $\mu\text{m}$  depth at intervals of 0.3 mm (80 lines per one inch) on the surface of the compound [C]. The stretching was not performed in Comparative Example 3. In Comparative Example 4, the inter-roll longitudinal stretching was followed by transverse stretching using a tenter oven (biaxial stretching). The surface layer side of the obtained sheet was then subjected to corona treatment at 50 W/m<sup>2</sup> • minute using a discharge treatment apparatus (product of Kasuga Electric Works Ltd.) to obtain a three-layered label.

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Table 2

5	Layer	Polyolefin		Fine powder		Thickness of layer (μm)	Stretching conditions		Stretching property
10		type wt%		type wt%			temp (°C)	stretching times	
15	Example 1								
20	(B)	(a)	92	(d)	8	2	120	6	good
25	(A)	(a)	99	(a)	1	86			
30	(C)	(e)	92	(d)	8	2			
35	Example 2								
40	(B)	(a)	98	(d)	2	8	120	6	good
45	(A)	(a)	96	(a)	4	74			
50	(C)	(e)	98	(d)	2	8			
55	Example 3								
60	(B)	(a)	92	(b)	8	4	140	3	good
65	(A)	(a)	99	(a)	1	132			
70	(C)	(e)	92	(b)	8	4			
75	Example 4								
80	(B)	(a)	92	(b)	8	5	130	7	good
85	(A)	(a)	99	(c)	1	80			
90	(C)	(e)	92	(b)	8	5			
95	Example 5								
100	(B)	(b)	92	(b)	8	5	120	4	good
105	(A)	(b)	99	(c)	1	120			
110	(C)	(f)	92	(b)	8	5			
115	Example 6								
120	(B)	(c)	95	(c)	5	5	125	4	good
125	(A)	(c)	100		0	200			
130	(C)	(f)	95	(c)	5	5			
135	Example 7								
140	(B)	(d)	95	(c)	5	5	115	4	good
145	(A)	(d)	100		0	150			
150	(C)	(f)	95	(c)	5	5			
155	Example 8								
160	(B)	(a)	92	(b)	8	8	120	4	good
165	(A)	(a)	99	(c)	1	74			
170	(C)	(e)	92	(b)	8	8			

Table 2 (continued)

5	Example 9							
	(B)	(b)	92	(b)	5	5	120	5
	(A)	(b)	99	(c)	1	80		
10	(C)	(f)	92	(b)	5	5		good
	Comparative Example 1							
	(B)	(a)	92	(e)	8	5		
15	(A)	(a)	96	(f)	4	80		no good (note)
	(C)	(b)	92	(e)	8	5		
	Comparative Example 2							
20	(B)	(a)	100		0	1		good
	(A)	(a)	92	(d)	8	88		
	(C)	(e)	100		0	1		
25	Comparative Example 3							
	(B)	(a)	92	(d)	8	5		
	(A)	(a)	96	(e)	4	80		
30	(C)	(e)	92	(d)	8	5		
	Comparative Example 4							
	(B)	(a)	92	(d)	8	5		
35	(A)	(a)	96	(a)	4	80		good
	(C)	(e)	92	(d)	8	5		
	(note) A lot of agglomerative projections and occasional breakage observed.							

## 40 (Test Examples)

[0055] The obtained label was tested and evaluated as follows.

## 45 1) Measurement of physical properties of the label

[0056] Opacity of the label was measured according to JIS Z-8722. Smoothness of the adhesive layer was measured according to JIS P-8119 and Clark stiffness according to JIS P-8143.

## 50 2) In-mold forming (fabrication of hollow container) and evaluation

[0057] The label was cut into 70 mm long and 60 mm wide, and then, as shown in Fig. 1, placed in a metal mold 2 (25°C) so as to contact the surface layer 1b with the inner wall 2a of the metal mold 2, and fixed by vacuum suction through vacuum suction holes 5. Then performed was label-attachable hollow forming using a high-density polyethylene HB-330 (product of Mitsubishi Chemical Corporation) at a parison temperature of 180°C and a shot cycle of 12 seconds, thereby to obtain a label-attached polyethylene container. Also a label-attached polypropylene container was obtained in a similar manner by label-attachable hollow forming using polypropylene EA-7 (product of Mitsubishi Chemical Corporation) at a parison temperature of 210°C and a shot cycle of 12 seconds.

[0058] Label attaching property by the forming, occurrence of blister and label adhesive strength of the label-

attached hollow container thus obtained were evaluated or measured by the methods described below.

2-1) Label adhesive (insertion) property

5 [0059] States of the label attachment resulted from each 100 shots of hollow molding were judged by the criteria as below:

- : all labels attached to a predetermined position without problem,
- △: no drop but dislocation of the labels, undesirable for the practical use, and
- 10 X: drop and dislocation of the labels observed during the attachment.

2-2) Occurrence of blister

15 [0060] State of the occurrence of blister in the label attached to each container was judged according to the criteria below, and evaluated by a total point for 20 containers (maximum 100 points):

- 5 points: no blister observed,
- 4 points: blister observed in less than 10% of the label area,
- 3 points: blister observed in 10% or more and less than 20% of the label area,
- 20 2 points: blister observed in 20% or more and less than 50% of the label area, and
- 1 point: blister observed in 50% or more of the label area.

2-3) Adhesive strength of the label

25 [0061] Four test pieces of 15 mm wide were cut out from the label-attached portion of the container, and peeling strength of the labels were measured using a tension tester Model RTM (product of Orientech Co., Ltd.) to obtain an average value.

[0062] Results of the individual tests were shown in Table 3.

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Table 3

	Opacity (%)	Smoothness of Adhesive Layer (C) (sec)	Clark stiffness Longitu-dinal/trans-vere	Label Adhesive Property	Polyethylene Container		Polypropylene Container	Blister Adhesive strength	Blister Adhesive strength
					Blister	Adhesive strength			
Example 1	10	300	38	18	○	98	500	97	450
Example 2	13	500	36	17	○	100	750	99	550
Example 3	16	1200	100	35	○	100	650	100	610
Example 4	12	1800	36	15	○	99	620	99	510
Example 5	17	1500	85	26	○	100	800	100	750
Example 6	19	1000	220	48	○	100	900	100	850
Example 7	16	1300	170	42	○	100	840	100	810
Example 8	13	120	34	14	○	100	480	100	400
Example 9	11	200	32	13	○	100	650	100	520
Comparative Example 1	13	90	33	13	○	45	30	85	200
Comparative Example 2	25	5000	38	16	△ (note)	70	80	75	100
Comparative Example 3	9	150	15	14	×	98	550	95	450
Comparative Example 4	50	9000	31	60	○	80	150	78	50

(note) Two labels were fed in a stacked manner due to inter-label blocking.  
(unit of adhesive strength:  
g/15 mm width)

[0063] As is clear from Table 3, the transparent labels of the present invention have opacity, smoothness of the adhesive layer (C) and Clark stiffness within preferable ranges and gave desirable results in all items of label adhesive

property during the hollow forming, blister suppressive property at the time of the attachment onto the formed container, and label adhesive strength.

5 [0064] On the contrary, the label (Comparative Example 1) using synthetic calcium carbonate with an average particle size of 0.15  $\mu\text{m}$  for the substrate layer (A), and heavy calcium carbonate with an average particle size of 3.3  $\mu\text{m}$  for the surface layer (B) and adhesive layer (C) showed a significant occurrence of blister since a low smoothness of the adhesive layer (C) resulted in a weaker adhesive strength between the label and the container. Breakage of the label during the stretching was also frequently observed, which was ascribable to a lot of secondary aggregates formed in the substrate layer (A) due to poor dispersion.

10 [0065] Any of the labels such that being produced without using the inorganic fine powder for the adhesive layer (C) and surface layer (B) (Comparative Example 2), being not stretched (Comparative Example 3) and being biaxially stretched (Comparative Example 4) was poor in the properties and lacked practical value.

#### Industrial Applicability

15 [0066] The transparent label of the present invention has an excellent transparency and is suitable for in-mold forming. Thus the label of the present invention is available as an in-mold label in, not only hollow molding, but also in injection molding, differential pressure molding and press forming, which ensures versatility and excellent industrial applicability thereof.

20 [0067] According to the method of the present invention, such label can be fabricated with ease.

#### Claims

1. A transparent film comprising a substrate layer (A) of a uniaxially stretched film containing 95 to 100 wt% of thermoplastic resin and 0 to 5 wt% of an inorganic or organic fine powder having an average particle size of 0.2 to 2  $\mu\text{m}$ , a surface layer (B) of a uniaxially stretched film containing 85 to 99 wt% of a thermoplastic resin and 1 to 15 wt% of an inorganic fine powder having an average particle size of 0.7 to 3  $\mu\text{m}$  and being provided on one surface of the substrate layer (A), and an adhesive layer (C) of a uniaxially stretched film containing 90 to 99 wt% of a thermoplastic resin having a melting point of 80 to 140°C and 1 to 10 wt% of an inorganic or organic fine powder having an average particle size of 0.7 to 3  $\mu\text{m}$  and being provided on the other surface of the substrate layer (A).
2. A transparent label as claimed in Claim 1, wherein the substrate layer (A), surface layer (B) and adhesive layer (C) comprise a film uniaxially stretched by 2 to 8 times.
3. A transparent label as claimed in Claim 1, wherein the thermoplastic resin contains a polyolefin resin.
4. A transparent label as claimed in Claim 1, wherein the thermoplastic resin contained in the adhesive layer (C) has a melting point of 80 to 140°C
5. A transparent label as claimed in Claim 1, wherein the thermoplastic resin contained in the adhesive layer (C) is an ethylene-base resin.
6. A transparent label as claimed in Claim 5, wherein the thermoplastic resin contained in the adhesive layer (C) is selected from the group consisting of ethylene-acrylic acid copolymer, ethylene-vinyl acetate copolymer and ethylene- $\alpha$ -olefin copolymer.
7. A transparent label as claimed in Claim 1, wherein the inorganic fine powder is selected from the group consisting of heavy calcium carbonate, precipitated calcium carbonate, fired clay and talc.
8. A transparent label as claimed in Claim 1, wherein the organic fine powder has a higher melting point than that of the thermoplastic resin and is non-compatible.
9. A transparent label as claimed in Claim 1, wherein a content of the organic fine powder having a particle size of 44  $\mu\text{m}$  or above is 10 ppm or below.
- 55 10. A transparent label as claimed in Claim 1, wherein the label has a longitudinal Clark stiffness of 30 to 250, and transverse Clark stiffness of 10 to 50.
11. A transparent label as claimed in Claim 1, wherein the label has an opacity of 20% or below.

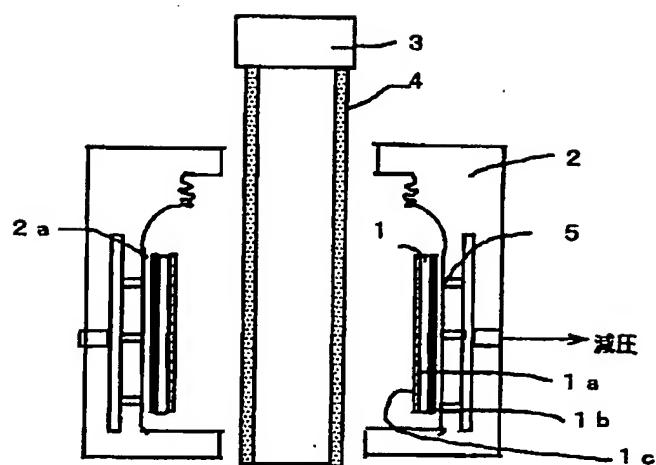
12. A transparent label as claimed in Claim 1, wherein the adhesive layer (C) has a smoothness of 100 to 2,500 seconds.
13. A transparent label as claimed in Claim 1, wherein the total thickness of the label is 60 to 250  $\mu\text{m}$ .
14. A transparent label as claimed in Claim 1, wherein the surface layer (B) and adhesive layer (C) respectively have a thickness of 1 to 10  $\mu\text{m}$ .
15. A transparent label as claimed in Claim 1, wherein the label is applicable to in-mold forming.
16. A transparent label as claimed in Claim 1, wherein the thermoplastic resin contained in the substrate layer (A) and surface layer (B) is selected from the group consisting of propylene homopolymer, propylene-ethylene copolymer and high-density polyethylene.
17. A transparent label as claimed in Claim 1, wherein the surface layer (B) has a print.
18. A transparent label as claimed in Claim 1, wherein the adhesive layer (C) has an embossing finish.
19. A method for fabricating a transparent film comprising the steps of: forming, on one side of a substrate layer (A) a surface layer (B) of a uniaxially stretched film containing 85 to 99 wt% of a thermoplastic resin and 1 to 15 wt% of an inorganic fine powder having an average particle size of 0.7 to 3  $\mu\text{m}$ ; the substrate layer (A) being made of a uniaxially stretched film containing 95 to 100 wt% of thermoplastic resin and 0 to 5 wt% of an inorganic or organic fine powder having an average particle size of 0.2 to 2  $\mu\text{m}$ ; forming, on the other surface of the substrate layer (A), an adhesive layer (C) of a uniaxially stretched film containing 90 to 99 wt% of a thermoplastic resin having a melting point of 80 to 140°C and containing 1 to 10 wt% of an inorganic or organic fine powder having an average particle size of 0.7 to 3  $\mu\text{m}$ ; and uniaxially stretching the obtained laminate.
20. A method for fabricating a transparent film as claimed in Claim 19, wherein the uniaxial stretching is performed by 2 to 8 times.
21. A method for fabricating a transparent film as claimed in Claim 19, wherein the uniaxial stretching is based on difference in the peripheral speeds between roll groups.
22. A method for fabricating a transparent film as claimed in Claim 19, wherein the embossing of the adhesive layer (C) precedes the uniaxial stretching.

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INTERNATIONAL SEARCH REPORT		International application No. PCT/JP99/05113
<b>A. CLASSIFICATION OF SUBJECT MATTER</b> Int.Cl <sup>6</sup> G09F3/02		
According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b> Minimum documentation searched (classification system followed by classification symbols) Int.Cl <sup>6</sup> G09F3/00-3/20		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Jitsuyo Shinan Koho 1926-1996 Toroku Jitsuyo Shinan Koho 1994-1999 Kokai Jitsuyo Shinan Koho 1971-1999 Jitsuyo Shinan Toroku Koho 1996-1999		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category <sup>8</sup>	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	JP, 3-88579, A (Oji Yuka Synthetic Paper Co., Ltd.), 12 April, 1991 (12.04.91) (Family: none)	1-22
Y	JP, 8-156157, A (Oji Yuka Synthetic Paper Co., Ltd.), 18 June, 1996 (18.06.96) & EP, 715953, A & US, 5570225, A & CN, 1130780, A & DE, 69505486, C	1-22
Y	JP, 6-332376, A (Oji Yuka Synthetic Paper Co., Ltd.), 02 December, 1994 (02.12.94) (Family: none)	1-22
Y	JP, 4-4121, A (Oji Yuka Synthetic Paper Co., Ltd.), 08 January, 1992 (08.01.92) (Family: none)	10,11
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.		
* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed		
Date of the actual completion of the international search 14 December, 1999 (14.12.99)		Date of mailing of the international search report 28 December, 1999 (28.12.99)
Name and mailing address of the ISA/ Japanese Patent Office		Authorized officer
Facsimile No.		Telephone No.